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TECHNOLOGY AND THE COST OF HEALTH CARE

HEARINGS

BEFORE THE

SUBCOMMITTEE ON
DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING, ANALYSIS AND COOPERATION

OF THE

COMMITTEE ON
SCIENCE AND TECHNOLOGY
U.S. HOUSE OF REPRESENTATIVES

NINETY-FIFTH CONGRESS

SECOND SESSION

SEPTEMBER 26, 27; OCTOBER 6, 1978

[No. 107]

Printed for the use of the
Committee on Science and Technology

U.S. GOVERNMENT PRINTING OFFICE
36-163 O WASHINGTON : 1979

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TECHNOLOGY AND THE COST OF HEALTH CARE

TUESDAY, SEPTEMBER 26, 1978

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING, ANALYSIS AND COOPERATION,

Washington, D.C.

The subcommittee convened, pursuant to notice, at 10:30 a.m., in room 2325, Rayburn House Office Building, Hon. James H. Scheuer (chairman of the subcommittee) presiding.

Mr. SCHEUER. Welcome to all of you and especially to our distinguished witnesses.

Today is the first of 3 days of hearings on "Technology and the Cost of Health Care." The subcommittee has been studying for over a year how the tools and techniques of medical science could be better used, so as to reduce costs and—at the same time—improve the quality of health care.

Last May, the subcommittee held hearings on "Computers in Health Care." At that time, many experts testified that, despite the general high quality of medical care in this country, billions of dollars are still spent in curative measures that are ineffective or of uncertain value.

Some of this problem is due to a lack of suitable information that could be used to keep score and evaluate the safety, the effectiveness, and the relative cost of medical devices and their uses. For that reason, several experts that testified in the computer hearings believe that the Federal Government should vigorously support the development of computer applications that would help in gathering the data and evaluating the cost-effectiveness of medical practices before they become entrenched.

The concern for costs, as well as for effectiveness, has grown as the Nation's health care bill has soared. Medical practice has become more sophisticated, more dependent on new technology, and very much more expensive. This trend has been stimulated by Government programs to bring more and better care to everybody. There are, however, improvements that could be made in how the Government invests in the development, evaluation, and use of health technologies, and most of these improvements would have a beneficial effect on both the cost and the quality of health care.

The principal aim of the improvements I have in mind would be to reduce waste and risk incurred by inappropriate use of medical techniques and devices, to eliminate gaps and duplication in the

development of health technology, and to apply a substantial research-and-development effort to preventive medicine.

It appears that such improvements could be implemented if there were a mechanism, within the Department of Health, Education, and Welfare, for assessing the impact of new technologies, evaluating the effectiveness of specific uses, and then carrying through on a coherent strategy for developing new devices and techniques. This strategy should include guidelines for the reimbursement through medicare and medicaid for the use of these techniques.

The Department of Health, Education and Welfare has recognized the need for some of these improvements and has initiated steps toward technology assessment and technology oversight within the Department. The House and the Senate have been working on bills that specify similar steps. The House passed its version just yesterday. All three approaches create a new Office of Health Technology whose minimum function would be to do evaluations and assessments and make recommendations to the Secretary.

The purposes of the hearings that we begin today are to: (1) understand how and why technology too often increases health costs; (2) identify ways to improve the cost-effectiveness of health technology—and control its inflationary impact on health care costs; and (3) explore how technology assessment, oversight, and management may be instituted by HEW, especially within the context of a new Office of Health Care Technology. Special emphasis will be given to the possibility that this office could play a crucial role in strategic planning and in coherent action programs, linking the otherwise independent divisions of HEW that have a stake in, or an influence on, new developments in health care.

In summary, we want to find out what steps can be taken by the Federal Government—and by the medical professions and supporting industries:

First, to alleviate those unnecessary costs and risks to health caused by the misuse of technology in modern medicine.

Second, to insure that we continue to develop those technologies—and their proper use—which are crucial to effective national health.

We have with us today four gentlemen, each distinguished in his own field, and representing four distinct interests in health care. We are delighted to have you here and look forward to a stimulating exchange.

Our first witness is Prof. Marc Roberts of the Harvard School of Public Health. Dr. Roberts is a professor of political economy and health policy. He also serves as director for the Harvard Seminars in Health Policy and Management that are designed to educate hospital trustees and people like Congressmen who have a layman's lack of expert knowledge but a deep concern and a serious interest in the health care field.

We are very happy to have you here with us, Professor Roberts. I look forward to what you are going to tell us today.

[The prepared statement of Marc J. Roberts, professor of political economy and health policy, Harvard School of Public Health is as follows:]

Testimony of Marc J. Roberts
Professor of Political Economy and Health Policy
Harvard School of Public Health

1) In recent years, we have increased the use of personnel, building and equipment to provide a single day of hospital care for a single individual. This trend, reflecting the diffusion of new technology, has been an important contributor to overall medical cost increases. Hospital costs are the largest single component of medical care costs and now comprise 42% of the total. In recent years, they have been increasing at a rate of about 15% per year. In addition, 22% of medical costs are represented by doctors' fees, much of which are incurred for services performed in hospitals. Not all of this is due to new technology. Some of the increase in hospital costs simply reflects the general rate of inflation. Some reflects the decline in lengths of stay--since average costs rise for shorter stays due to the costs of admission and initial testing. Some reflects the fact that hospital wages have been rising faster than those in other sectors--to the point where once underpaid hospital workers now earn as much or more than those who do similar work elsewhere. But some clearly reflects the widespread adoption of new technology. This is reflected in the increased use of inputs (plant, equipment, people) used to produce each patient day. Such input increases account for almost 3/4 of the increase, above general inflation, in the cost per average patient day. Much of the cost is incurred in increased use of and charges for ancillary services like diagnostic tests, x-rays, etc..

2) The cost-increasing effect of technical change in medicine has occurred because only some kinds of technical change have been pursued and not others.

We can distinquish among three kinds of technical change in medicine:

- o cost-reducing technical change
- o cost-effective improvements to quality
- o cost-ineffective improvements to quality

Unlike other industries in which cost-reducing technical change is often important, we see relatively little such change in medicine. If there were more of it, the quantity of inputs needed to produce a patient day in a hospital would be going down instead of up. Instead, most emphasis in medicine has gone to quality-improving technical change. This takes several forms. Some is embodied in new capital equipment (e.g. C-T scanners). Some is embodied in new drugs. Some is in the form of new procedures like coronary artery bypass graft surgery. In practice, whether a new machine, drug, or procedure is or is not cost-effective will depend on when and where it is used. Innovations that are cost-effective when applied to properly selected and limited patients will become cost-ineffective if they are diffused too widely and used too frequently. There are also some innovations which on further study turn out not to be appropriate for any significant population, i.e., those that can never be cost-effective perhaps because they are not really effective at all.

3) Technical change in medicine has emphasized quality improvement, often employed to a point where it is no longer cost-effective, over cost-saving, because of the pattern of incentives in the medical care system.

Economic studies of technical change in many industries suggest that much research and development effort is made by those who can expect to gain the most from it--and is oriented to producing those gains. Thus, new equipment is usually developed by equipment manufacturers, not equipment users, since manufacturers could gain greatly from the sale of new machines. Technical change in medicine fits into this pattern--with some exceptions. Much drug research is done by drug companies. New x-ray or laboratory equipment is developed by those manufacturers. New procedures which are not "embodied" in any saleable capital goods are necessarily developed by potential users--i.e., physicians and surgeons themselves. However, there is also a great deal of basic research in medicine which occasionally does yield new drugs or procedures which is not governed by market incentives. Instead, it is supported by federal and foundation grants, which tend to reward scientific excellence apart from practical payoffs.

Nowhere in this system has there been much incentive for cost-reducing technical change. Instead, many features of the system encouraged the development and cost-ineffective overuse of quality enhancing new technology. Indeed, the incentives to innovate can be so strong as to lead to new devices, drugs, etc., which on more careful study turn out simply not to be helpful to patients, apart from their costs.

o Many decisions on new technology are made by doctors who by reasons of convenience, status, training and a desire to serve patients, have opted for the newest and fanciest.

o With widespread hospital insurance, consumers have had little or no incentive to price shop, or to prefer less elaborate and less costly care if there were any possibility that it would also be less effective.

o Administrators of hospitals that enjoyed cost-based reimbursement also have had no reason to pursue cost-reducing technical change. In addition, to attract and retain the loyalty of a high quality medical staff, they have had every incentive to obtain the newest or the most advanced, even if it cost more.

o Hence, device, equipment and drug manufacturers have had no incentive to try to develop cost-reducing technical improvements because they are unlikely to be able to find a market for such products.

o Similarly, grant supported research by doctors and related scientists has focused on new scientific knowledge and/or new procedures. Funds, training and professional status all reward such efforts as opposed to those directed at cost-reducing new technology.

o Even where new technology has lowered the cost of providing a given unit of service (e.g., automatic analyzers for laboratory chemistry tests) these same dynamics tend to encourage expansion of use to the

point where total costs rise as a result.

o Similarly, competition among hospitals and a lack of regional planning can lead to over-investment in new equipment and financial pressures to then overuse it in a cost-ineffective manner in order to recover its costs.

4) Public policy objectives for medical technology should include both the increased promotion of cost-reducing technology and limiting the use of quality-enhancing developments to those contexts in which they are cost-effective. These ends are as important, or more important, than simply keeping out harmful drugs, devices, etc..

Much of the discussion of the social control of medical technology has focused on the "harm preventing" question. The possibility of an analogy to the F.D.A. with regard to screening non-drug innovations has been widely discussed and has recently been pursued in Congress. But from the point of view of the role of technology and medical costs, this problem is not the most important one. Instead, the more positive step of providing new incentives for cost-reduction is critical. So is the need to find ways to control the extent of investment in and use of desirable new machines, drugs and procedures so that they are only used where cost-effective.

5) Recent regulatory and policy changes in the health care area are going to provide some desirable new incentives.

Recent concern over medical care costs has lead to a whole variety of new regulatory and planning innovations. These seem likely to place limits on hospitals and doctors and in turn make them more concerned with cost control. The latter, in turn, should then be more receptive to cost-cutting innovation which will then provide incentives to manufacturers to engage in research oriented in that direction in the hope of producing saleable products.

- o Prospective rate reimbursement, including total revenue "caps" force institutional attention to cost control. A good number of hospitals have begun to improve their managerial and budgeting systems (e.g., to introduce service-by-service cost center accounting) in order to track and control costs in response to these external pressures.
- o Certificate of need review in some states has moved just from a focus on beds to the cost per bed and to the installation of new capital equipment. This has provided incentives for joint planning, sharing of services, and even multi-institutional systems designed to produce cost savings by avoiding competitive duplication.
- o Competition to the conventional fee-for-service system from H.M.O.'s can also produce cost-containment incentives. Such competition can foster new cost-reducing technology--but even more has shown itself able to limit inappropriate overutilization.

6) There are various steps Congress could take to provide additional incentives to foster cost-reducing technical change and to limit quality-enhancing change to cost-effective uses.

- o A system of research grants for research and demonstration projects for cost-reducing new technology.
- o A system of substantial annual prizes for the most promising new cost-reducing technological development demonstrated in the previous year.
- o Funds for research to evaluate the cost-effectiveness of new devices, equipment, procedures, etc. and perhaps the creation of an ongoing center to carry out such work within N.I.H..
- o Link the results of such studies to the development of proposed guidelines for PSRO's on the appropriate extent of the use of new technologies, and for HSA's, on the appropriate levels of investment in them in each region.
- o Funds to develop and implement new teaching materials to teach medical students and others about design theory and other analytical techniques helpful in making more careful resource allocation decisions.
- o Allow medicaid and medicare programs to pay providers on the basis of regional average costs for given services or procedures and not the institution's actual costs, thus providing added cost control incentives.
- o Encourage state rate setting authorities not to allow the automatic pass-through of all new capital investments into rates--again to give institutions reasons to purchase less costly equipment and hence give manufacturers more incentives to develop such devices.

STATEMENT OF DR. MARC J. ROBERTS

Dr. ROBERTS. Thank you very much, Mr. Chairman. It is my pleasure, indeed, to be here this morning to contribute to your hearings on medical technology.

What I would like to do this morning is leave you with a relatively simple message. As you so aptly put it in your opening statement, the question is not whether we should be for or against improvements and increasing technology in medical care, but rather what kinds of technology in the medical care area are in the public interest? Also, what can Congress do to improve the extent to which we develop and use appropriate, as opposed to inappropriate, technology.

We have to begin with the realization that what brings us here this morning is, in part, the recent rapid rise of medical care cost to which hospital costs are an important contributor.

Hospital costs are now 42 percent of medical care costs, and have been rising at about 15 percent annually. This rise is attributable not simply to inflation and input prices, not simply to higher wages and higher fuel bills and so on. Much of it is attributable to the fact that hospitals now use more inputs to produce each patient day. We now have more people in the hospital per patient, more equipment, more invested in plants than we did 10 or 15 years ago.

Mr. SCHEUER. Do the more people add anything qualitative to the health care that wasn't added before, or is it just more people there to provide routine functions? Sweden operates with, I believe, 1.1 person per hospital bed, and we operate with something like 4.3 people per hospital bed. I wouldn't think that much of that difference is made up by sophisticated health providers that are present in this country but are not present in Sweden.

Is it simply inefficiencies and featherbedding, or is it that we have substantially increased real top-quality health professionals who were not available before?

Dr. ROBERTS. I think the answer to your question, Mr. Chairman, as most academics answer most questions, it depends.

Mr. SCHEUER. That's an extremely helpful answer. [Laughter.]

Dr. ROBERTS. There are certainly situations in which we have had what you characterized as featherbedding.

Hospital administrators in a situation in which they have not faced incentives to control costs, have had no reason to oppose requests from department heads for additional personnel whether a routine or nonroutine sort.

In a climate in which there is no incentive for cost control, it is easy for supervisors to find things for people to do. On the other hand, much of the expansion in personnel in the hospitals which I have studied in any detail does come from people who are associated with particular new functions that the hospital has taken on.

Ten years ago we did not have a staff of respiratory therapists in a major teaching hospital because we did not use respiratory therapy as it is known today.

Fifteen years ago we would not have had individuals running CAT scanners because there were no CAT scanners. So some of the increase in personnel comes about because some new technology carries with it new people to be employed.

It is one of the ironies of the pattern of the health care technology, that much of it, instead of saving on personnel, leads institutions to use additional personnel. Instead of capital substituting for labor, capital is a complement for labor, and we wind up with more of both than we started.

I want to make a distinction between two kinds of technology or technological change. One kind is cost-reducing technical change. New ways to do what we used to do with less input. This is the sort of technical change we are familiar with when Alcoa announces they have found a way to produce aluminum for 25 percent less electricity. That is plain old cost reduction.

The other kind of technical change allows us to do things which we could not do before, or allows us to do things we could do before, but now slightly better, often substantially more expensively. This is quality-enhancing technical change.

One of the ironies of the medical care system is that all the incentives in the system have been in the direction of fostering the second kind of technical change as opposed to the first. And that, I contend, is a large part of our problem.

The question arises, why should we be against quality-enhancing technical change? Shouldn't society be in favor of a much higher quality, and as high a quality in medicine as possible? The answer to that question can only abe given if we realize that resources devoted to quality-enhancing changes are not free, they come from somewhere.

When the citizens of a State spend more money on Blue Cross premiums in order to pay for new X-ray equipment and new laboratory equipment in the hospital, that costs money they could have had available to spend on private concerns, or it is less money the State has available to spend on education or roads or other things.

So the question is not simply, is new technology beneficial? Rather, the question is, Is it beneficial enough, considering the cost? Is it, in fact, cost effective?

I noted in your opening statement, the way you posed the issue accepted this as the right way to think about the problem; it raised issues from a cost-effective point of view. Unfortunatley, until very recently the whole notion of cost-effectiveness has not been the basis on which most medical decisionmaking has proceeded. Instead, medical decisionmaking has been dominated by what has been called "the quality imperative": if it seems possible, and might do any good for the patient, no matter how small the probability and how large the cost, let's do it.

That is not cost-effectiveness. It is simply looking at the possibility of effectiveness. That decision criterion systematically leads us to the socially wrong answer; it leads us to make decisions to supply devices or procedures for therapy at very high cost with very low effectiveness.

Mr. SCHEUER. When actually there is a finite amount of resources that can or should go into health care.

Dr. ROBERTS. Exactly. And the quality imperative, in part, means that——

Mr. SCHEUER. That we are misallocating resources within the health-care system itself.

Dr. ROBERTS. Even within the health-care system. In fact, if we want to provide the most health benefit for the Nation, cost-effectiveness is the most effective way in which to proceed, because, otherwise, we will find very costly and not very effective medical procedures will drain health resources from other more cost-effective areas.

Now, why have we been in this situation, why do we have all of this quality-enhancing technical change, and why is it that we tend to overuse it? After all, quality-enhancing technical change, new machines, CAT scanners, kidney dialysis, new drug therapies; many of these things are excellent in their place, excellant if not overused. So why do we tend to overuse quality-enhancing technology, and why do we have so little technical change oriented to cost reduction?

The answer to this lies in the structure of incentives that we have created in the health-care system. But it is through the working of many interacting parts; any attempt to pin the blame on any one part is inappropriate.

The health-care system reminds one of an ecologist's conception of a swamp in finely balanced ecological equilibrium, where the little bugs are eaten by the big bugs, and the big bugs are eaten by the little fish, and the little fish are eaten by the snakes, and the snakes are eaten by the racoons, and the racoon droppings fertilize the trees, and the trees give food to the bugs.

That sort of very finely balanced web of interdependency is exactly what characterizes the health-care system. On the consumer side; first of all, consumers by-and-large cannot tell very much about the quality of medical care which they are receiving; second of all, given the current patterns of financing have little incentive to worry about cost. So unable to judge quality, and with little incentive to worry about costs, they are not a force for cost-effectiveness in the system. Consumers go into hospitals often with coverage for a large part of their hospitalization expenses. They choose doctors, and doctors have limited hospital privileges. The hospitized consumer by and large is hopitalized where it is convenient for the doctor. So the consumer very often doesn't have any choice about picking the hospital.

And the consumer is typically not in the position to say to the doctor, "I would like to go to hospital X instead of hospital Y because hospital X has spent a little less on fancy X-ray equipment and so its charge for X-rays is a little smaller." The consumer is not in a position to know, he is not in a position to make the trade-off, and he has no incentive for doing so, anyhow.

On the supply side, consumers have no incentive to push people to make the cost-effectiveness trade-off and neither doctors nor hospital administrators have the incentive in the direction of cost-effectiveness. Doctors, by training, are oriented to the quality-imperative that I discussed earlier: "When in doubt try it." Furthermore, professional status and/or keeping up with the frontrunners in medicine demands the latest and most advantageous equipment.

Furthermore, for a doctor who conscientiously seeks to act as an advocate for his patient, when the patient is ill and technology is available, it is in a sense appropriate for the doctor to wish to

employ the maximum amount of technology for the patient's benefit.

Mr. SCHEUER. This urge to do everything no matter how little the payoff and how great the cost—is it being enhanced or encouraged by the problem of medical malpractice? It's the practice of defensive medicine?

Dr. ROBERTS. I think there is no question but that it is. I think it is also encouraged by the fact that doctors preceive that patients have widespread insurance coverage.

If a doctor realized that that pattern of practice had substantial cost to the patient, the doctor, as the patient's agent, might have second thoughts. But, since the added tests have no cost to the patient, there is no persuasive reason not to order them. There is also often the mistaken notion that doing more can only produce benefits—that it cannot produce harm. On the contrary, however, we know that it's perfectly possible to overprovide services to patients.

A clear example of this is information about the effect of the length of hospital stay on the patient recovering from a heart attack. We know it's better for a patient to spend less time as opposed to more time in the hospital, that they recover quicker.

We also know that exploratory surgery, and even the simplest surgical procedures, like tonsillectomy, occasionally produce adverse reactions under a general anesthetic, and that there is some, albeit small, mortality risk for having your tonsils out or having your wisdom teeth removed.

We know that drawing blood samples, every once in a while, can lead to infections that can even be life-threatening.

So there are costs as well as benefits from using technology.

There is, for example, a controversy developing among kidney transplant surgeons about how much immunosuppressant medication to provide to patients. People in California who run a very large transplant service contend that other people provide too much, that less medication produces better results.

So there is evidence for cases in which we have gone too far. And there is evidence to say that our decision rules occasionally lead us to over-prescribe.

Hospital administrators, meanwhile, have no incentive to control the doctor-patient/alliance that favors increased technology. Administrators want to attract doctors; doctors are attracted by high-quality technology. Having doctors is a way of making sure that you have enough patients; having patients is a way of making sure that your hospital fulfills its financial commitments. So administrators obligingly respond to doctors by installing new equipment when doctors request it from them. In addition, the administrators' professional status and career incentives are all in favor of successful expansion, raising the status of the staff, increasing the technology available and so on.

The problem that this finely adjusted system creates is that no one has any reason to produce cost-reducing technology.

What we know from every economic study of technical change in industries as diverse as railroads, or aluminum, or aircraft, or whatever, is that investment in research and development of new

products and processes is undertaken by people who plan to make money from it.

But as long as hospitals and doctors are not interested in reducing costs, manufacturers don't have a market for potential cost-reducing innovations. And as long as they don't have a market for cost-reducing innovations, they have no incentive to spend their research money to find ways to cut costs. Consequently, we have had a misdirection of private-sector research funds into quality-enhancing, as opposed to cost-reducing, technology.

Mr. SCHEUER. It seems to me it is not necessarily an either/or question. When they produce the quality-enhancing technology, there seems to be little pressure on them to design into it cost-reducing elements. But, there must be opportunities for that.

Dr. ROBERTS. They have particularly little incentive to add to their product lines equipment whose performance may be slightly less than the maximum but whose costs are significantly less than the maximum.

It may be, indeed, that the same research that would produce the maximum performance machine would also support something less than the sports-car model. You know, the plain old Chevrolet that gets you around town but doesn't go quite as fast in an emergency.

But there is no market for the "Chevrolet"; there is only a market for handcrafted sports cars in medical technology. So, even if the information is available, the products tend not to be marketed because there is no market for them.

Similarly, public funding for research and development is not oriented markedly in the direction of cost-reducing technology. It is true that some Federal funding efforts in areas like computer-aided diagnosis, the use of computer-aided protocols, or the use of paraprofessionals really does represent investment in cost-reducing technical change. New technologies that allow you to substitute cheap labor for expensive labor is cost-reducing technical change—and the Federal Government can take credit for having spent some money appropriately in that area. But by and large the vast bulk of money available through Federal Government programs to support medical research goes in the direction of quality-enhancement, pushing back conceptual and scientific frontiers. And there is little money available for people who want to find a way to make a machine cheaper, to lower dosage rates, to reorganize a hospital staffing patterns, and so on.

That is not glamorous work; it's not high-technology science, and it's not an area that has received the sort of extremely generous support that we have given to fundamental, biomedical science.

Now, the question for this committee and for the Congress could ask what one might do to restructure the system of incentives in order to provide for the appropriate limitation of quality-enhancing technology, and for the encouragement of cost-reduction technology.

The usual suggestion any witness makes to a congressional committee when faced with a problem is how the Government should spend money in one way or another—and I must say, I am no exception this morning. One obvious step would be to begin to provide money for research and demonstration projects on medical-care cost-reduction.

Much of what we need in this area is not fundamental research but development and application of already-understood principles. And some Federal dollars could be helpful.

An alternative, or supplement, to research grants would be a scheme of annual prizes. It seems to me that part of the problem we have is a prestige-recognition/public-attention problem. And I think that one might appropriately focus the attention of the Nation on the problem of hospital cost reduction if the Congress were to establish a series of annual $10,000 or $25,000 prizes for significant contributions to medical-care cost reduction, announced with appropriate fanfare in the Rose Garden.

In addition, it seems to me that the whole question of supporting our capacity to do cost-effectiveness evaluation of new devices, procedures and therapies is a critical one. The underlying intellectual and conceptual basis for doing cost-effectiveness research on new therapies and procedures is certainly less well developed than one would like. Nevertheless, I think it is appropriate to try to use them as best we can, because the alternative is staring at the corners of the room and relying on intuition. The techniques are superior to intuition even if they are not as well developed and as carefully critiqued as we would like.

Furthermore, we have a tremendous backlog of procedures, devices and patterns of practice that have never been subject to cost-effectiveness tests. It would be highly desirable in my judgment to subject the traditional body of patterns of clinical practice to cost-effectiveness evaluation.

Part of the problem in this area is that until recently, and perhaps not even now, doctors are not comfortable with the concepts of modern decision theory, with the notion of cost-effectiveness, with the whole intellectual apparatus or decision trees, conditional probabilities, and so on. It has never been a part of the traditional medical school curriculum to conceptualize clinical decisionmaking in this way.

In part for that reason, research that has been done on clinical practice is often reported in a way which makes it extremely difficult for someone from a decision-theory point of view to figure out what is even going on, because the whole project has not been set up to generate the right kind of data.

I've been part of a study group that has attempted to reconstruct clinical decision trees for a number of common procedures, and we have found when we looked at the literature that many of the well-known studies simply didn't provide appropriately developed and focused information.

In correcting this difficulty, it seems to me an incentive, as opposed to a regulatory, approach is appropriate.

And I would personally like to see some congressional action encouraging the development of new curriculum and new teaching materials in medical schools to foster attention to cost-effectiveness through decision-theory thinking by physicians.

Mr. SCHEUER. I have one problem with what you are saying. You are saying that the Government should intervene to do some few little positive things; more R. & D. money; doing something about the decision tree; helping raise the level of consciousness on cost as well as quality of health care in medical schools.

It seems to me that we have got to do something to the system to make this self-correcting on a large scale. We cannot do it by a little project here to encourage this, and another little project there to encourage that. We have to create incentives out there. As you have said, we have a built-in incentive in the private sector, which is making money. At the bottom line, you win or lose the game depending on whether the ink is red or black. And that affects decisionmaking up and down the line. At every point in the process, there is concern about cost versus quality of product. How do we crank that same kind of incentive into the health game?

I can give you a couple of examples. There have been suggestions that we simply have to put a cap on health-care cost. And we can do this by region. We can say to the New England States, "You have got 5 percent of the population; we are spending $200 billion on health-care, so you have got $10 billion next year and we are going to hold you to $10 billion for 5 years, with only an inflation corrective. You are just not going to continue increasing health-care cost by 15 percent a year, or whatever it is, at twice the rate of inflation. Now, you are in business for yourself; here is your $10 billion."

That would have a powerful effect on people's minds. Every decision they made to spend enormous amounts of money for a modest increment to health-quality, they would know that those dollars came out of the common pot. It is the economy of the close. Do you know what I mean by that?

Dr. ROBERTS. Yes, exactly.

Mr. SCHEUER. How do we build in a consciousness of the economy of the close here, and what are the various modalities—and my apologies go out for using that word—what are the various ways we can weave it in? And not the bandaid business of giving a little grant of $10,000 for somebody to——

Dr. ROBERTS. I was going to come to exactly the same conclusion that you have reached. These positive efforts to facilitate the response of the system will not by themselves be sufficient to change the behavior of the system. They will only be effective in the context in which people have system-based incentives to apply for the grants, to look at the results of the new technology. Then they could do it themselves. They could think three times before spending a substantial amount of money on the chance that it may provide some iota of improvement.

You asked me what were the major ways in which we could restructure the system to provide additional incentives. I think it is worth pointing out that a series of recent initiatives the State and Federal governments have taken have clearly begun this job.

You mentioned the possibility of either State-by-State or region-by-region caps on total medical revenues. I, myself, think that is an extremely promising approach, recognizing that implementing it is fraught with various kinds of difficulties. There is the question of what basis upon which to set the cap; is it a region, a State, an institution? Then, once you set a geographic basis for distributing the cap money, you are relying on the internal processes of whatever group you have given the money to allocate it within the area. And those internal processes may not produce socially beneficial outcomes.

If you give the money to a hospital and say, "You only have so much," the hospital may, in a sense, turn it over to bargaining among the chiefs of various clinical services. And their balance of political power may not exactly reflect society's interest in diverting resources in one direction as opposed to another.

Mr. SCHEUER. Another way to do it, although I really haven't thought it through, would be to cut back a progressive percent of the health-care cost within say tertiary hospitals across the country for the next 5 years and then leave it up to them.

Now, this is sort of a horizontal slice instead of a vertical slice. Some basic decisionmaking could be done by Congress on shifting the balance between one type of hospital or another.

I presume that we would provide a larger percentage of health-care cost for community-based, low-technology, preventive-health-oriented ambulatory care as a substitute for high-technolgy oriented, hospital-based bed care.

Congress might make some rough judgmental inputs that way, and then leave it up to the various medical constituencies to sort it all out.

Dr. ROBERTS. I think this is a solvable problem.

The problem of how one would construct the most effective possible cap system is a solvable problem; exactly because the alternative, which is to continue under the present regime, is even worse. One doesn't need a perfect system. One needs a system which is sufficiently attractive to make it look good against what is current practice, and that is not a terribly high standard for comparison.

I do think there is something in what you have said that we have to be very careful about. There was an equation in what you said between ambulatory care, low-technology, in community service and community hospitals.

Mr. SCHEUER. Neighborhood health clinics, rather.

Dr. ROBERTS. I would caution that certain kinds of ambulatory care are no lower technology than certain kinds of hospital care. The whole development of computer-based/multiphasic outpatient screening is a high-technology approach to ambulatory care. So one has to be careful in that regard.

Similarly, despite assertions of the major teaching hospitals that they are in a qualitatively different business than the community hospitals, studies of the Boston teaching hospitals that have been done by the Massachusetts Department of Public Health indicate that a substantial number—and in some cases a majority—of the patients in the most prestigious hospitals, are essentially there as community hospital patients with community hospital complaints.

So the distinction between——

Mr. SCHEUER. And could be treated at a community hospital with far less in the way of CAT scanners and open-heart surgery and all that.

Dr. ROBERTS. It's not clear that the pattern of practice in community hospitals for less acute cases is all that different than the pattern of practice in teaching hospitals. It is clear that the cost in teaching hospitals tends to be substantially higher than the cost in community hospitals.

Mr. SCHEUER. Because of the teaching element that is now fed into the mix? Or because they perform services less efficiently; the

same service that community hospitals provide but with less efficiency?

Dr. ROBERTS. This one of those questions I suggest we need to do more work on. Hospital accounting systems have been sufficiently primitive or are not oriented to giving you accurate cost-of-service information, so it is very difficult to know whether or not performing certain services is, in fact, more costly in a teaching hospital, or whether it just shows up more costly because of the arbitrary rules we have for allocating overhead and dividing things up.

And the hospitals, given the way the reimbursement systems work, don't necessarily have incentives to develop cost-accounting systems that would even allow us to make appropriate comparisons. So, absent any hard information, I cannot answer your question accurately.

My impression is that the high cost of teaching hospitals is due primarily to two things: One, in various subtle ways the cost of the teaching program winds up being borne through patient care. Whether it's the cost of having higher levels of staff to supervise the students, whether it's the cost of running ancillary tests because students tend to order a great deal of diagnostic tests as part of a learning process, or whatever, that is part of the explanation.

The second part of the explanation is that the high technology aspects of teaching hospitals impose substantial central administrative costs. And the rules we use for allocating central administrative costs among different services tend to, in effect, hide that burden by reallocating the central administrative costs of high technology specialized services onto the broad base of hospital patients as a whole.

In other words, to support the elaborate massive coronary care/intensive care units and cardiac catheterization laboratories and a whole variety of lab and X-ray technology, and special laboratories to run an operation of that complexity requires a larger central administration. And then what you do is allocate the central administrative services on the basis of floor space or personnel or another index which does not take into account the disproportionate burden.

We have a hospital pricing scheme which does not reflect the cost of differential services, in part, because we don't know the cost of differential service nor what the costs of new technology really are.

There is new work beginning to get underway, some of which my associates and I intend to carry out, that I think will make some progress on these issues, but the available data right now is really quite terrible.

Other alternatives for attempting to create a system-based incentive of the sort you referred to, Mr. Chairman, are already underway.

First of all, the apparatus of the health planning process has begun to put some incentives on people, at least in regard to the question of duplication of facilities. Initially, health systems agencies and related State health planning agencies focused primarily on the number of beds that hospitals proposed to construct, compared to the number of beds they perhaps proposed to take out of service.

One consequence of this was that it was possible for a hospital to replace a large number of low-technology beds with a small number of high-technology beds, increasing costs in the bargain, and have the planning agency claim a great victory for having diminished a great number of beds.

There is evidence in the literature that States with tight certificate-of-need laws did succeed in lowering the number of beds, and, simultaneously succeeded in raising the amount of capital invested per bed as part of this process.

As we move to more mature health system agencies, they have become more sophisticated about technology and have begun to worry about the technical intensiveness of alternative kinds of investments, and they have begun to focus on equipment as opposed to just beds. This has provided an incentive to many institutions to think about shared services in order to fully utilize any new technology that is available.

Shared services is important from the point of view of reducing the overutilization of quality-enhancing technology to the point that you become cost ineffective, because if we install many machines or devices of a given type, the incentive then becomes to use them even in those cases in which they are not really cost-effective in order to provide enough revenue and enough volume to justify the decision to invest in the equipment in the first place.

So there is some reason, therefore, to try to ration the investment in certain kinds of new technology on a regional basis. Hopefully as the HSA's begin to come up to speed, they will engage in this question. Unfortunately, the HSA's themselves do not have appropriate incentive to ration the flow of health-care resources to their region. Instead, it is quite possible for the HSA's to act as regional advocates. "Let's have more here."

One system-based change we could make is to try to make sure that the Blue Cross/Blue Shield rates, or even State tax rates with regard to the medicaid component, were assessed on an HSA-by-HSA basis so that an HSA which succeeded in limiting the health-care cost in its area would get some gains for its citizens by doing so.

Now, if an HSA lowers cost in an HSA region, it has to share its reward with other regions of its State. If an HSA has a quarter of the State, the HSA citizens only get a quarter of the gains. Three-quarters of the gains go to the other three-quarters of the State, because the finance is on a statewide basis. If we could find some way to map the financing decisions more closely to the political decisionmaking with HSA's, we might provide some incentive to strengthen the planning process.

A second kind of incentive we could provide has to do with the common practice in rate-setting agencies of what is called "capital passthrough." Many States, as you know, have State rate-setting commissions, many of which, in effect, operate what amount to revenue caps on a hospital-by-hospital basis. Massachusetts, Rhode Island, Connecticut, and others.

Those systems tend to allow you a certain percentage increment over last year's cost based on some sort of deflated formula. Part of the difficulty is that any new capital investment which is approved by a certificate-of-need agency is, in most States, automatically

passed through into the hospital's reimbursement base, so that the rate-setting process itself provides no incentive for cost reductions.

The most plutonian measure possible, which is probably not politically feasible, would be simply to say "no capital passthrough." You have no incentive to make an investment that would raise costs because you simply won't be able to recover it.

A total end to capital passthrough is the most extreme measure. There are the less-extreme devices which would, nonetheless, provide some incentives. For example: One could eliminate from certificate-of-need review any proposed investment project which would not carry with it a rate-increase proposal. So that you, at your option, could be exempted from the certificate-of-need review process, provided you were confident that this was going to be a cost-reducing innovation. That might provide a big incentive to hospitals who are worried about the difficulties of certificate-of-need review.

Another incentive which we could provide, which goes with your point about the differential cost between community and teaching hospitals, and which, in part, is at Congress' disposal, is to change the way in which medicare and medicaid pay providers. Today they pay providers different sums of money for the same procedure, depending on where it occurs, based on the cost incurred in different settings.

This is an unusual feature of the hospital industry; the Government rewards high-cost producers by buying services from them at high costs, and penalizes low-cost producers by buying services from them at low cost, instead of the way it buys automobiles or anything else. It buys those things at a given price, and if they are too costly they cannot compete for the business.

The introduction of a normal prudent buyer's business principles into the purchase of service for medicare and medicaid patients seems to me an interesting avenue to explore. It would imply that State medicare and medicaid agencies would set dollar values on what they were willing to pay for certain kinds of procedures based, perhaps, on the distribution of costs from institutions in the area. And then we would tell high-cost institutions that either they could provide the service at the same cost that it was provided in other places, or they could forego the patient load.

Mr. SCHEUER. I can hear a wail coming through the air from certain cities with all those high-cost tertiary hospitals at the very suggestion you have just made. Can't you hear it?

Dr. ROBERTS. Yes, I can hear it.

I should point out for the committee's information that I am a trustee of the Massachusetts General Hospital, and I know what distress such a proposal would cost that institution.

Nonetheless, from the perspective of providing system-based incentives, it seems to me it is an appropriate device.

In defense of the teaching hospitals, it does seem to me that if we are to do this we are, alas, going to have to think about new ways of simultaneously funding postgraduate medical education because, essentially, we have come out with a system where we cross-subsidize the funding of postgraduate medical education through the medicare and medicaid system and through Blue Cross rates.

Mr. SCHEUER. In other words, if you want to pay medical students in hospitals, you ought to face up to that and provide funds directly for that?

Dr. ROBERTS. Exactly, and disentangle this currently complicated relationship.

Mr. SCHEUER. And it should be looked upon as part of the cost of medical education and not as a part of the cost of service.

Dr. ROBERTS. And we could make a clear decision as to what extent we want to finance the training of different postgraduate specialties out of the public purse, and to what extent we expect people to go into debt to finance their own training in anticipation of later income.

Mr. SCHEUER. And as part of that funding for the training of young doctors and interns, there ought to be some kind of payment to the patients at that hospital for the 17 examinations that they have to go through from successive groups of interns who are engaging in their medical education. [Laughter.]

Dr. ROBERTS. Part of the difficulty of moving to a system of payments based strictly on procedures is that it does raise the specter of a return to the more traditional pattern of two-class medicine. One of the great virtues of the medicare/medicaid system is that it has tended to soften the distinction between the traditional charity patient and the private pay patient. It has diminished the traditional gap in the quality of service and attention received.

One has to recognize the possibility that certain institutions will opt out of providing care to those patients if one moves in this direction.

Mr. SCHEUER. There could be some direct compensation for that institution, if the Congress and the executive branch would want to do that. At least they would be aiming at the problem through a high-powered rifle with an 8-power scope and not with a 12-gage shotgun.

Dr. ROBERTS. I couldn't agree more.

And in support of that contention I will quote the associate dean of a medical school, other than my own, who will remain nameless. He said that he had recently urged his colleagues to continue to rely on the health-care dollar and not on the education dollar for the financing of postgraduate medical education in order to prevent the Congress from beginning to monkey with the pattern of postgraduate medical education.

That is the obverse of the high-powered-rifle image.

Mr. SCHEUER. Yes.

Dr. ROBERTS. Another thing that we could usefully do is provide increased technical support to both the HSA's and the PSRO's with regard to the questions of how much capital investment is reasonable in an area, what specific technology is appropriate, and how much use of the technology on a given population is to be expected.

Partly in response to political pressure, Congress chose to decentralize the formal legal standard function of both HSA planning and the PSRO quality review process. Those standards and criteria are now set on an agency-by-agency basis. But the problem of trying to figure out what makes sense with regard to how much to build and how much to use is inappropriate for 150 small agencies

scattered around the country, each trying to solve it on their own, independently. Congress could make a positive contribution by supporting work which would then be assessible to the HSA's and PSRO's and could serve as a guide in the standard-setting process.

That concludes my testimony this morning, Mr. Chairman. I will be happy to answer any further questions.

Mr. SCHEUER. We thank you very, very much, Dr. Roberts. Your testimony has been very thoughtful and very persuasive.

With so much money being spent on Government R. & D., I have trouble understanding why we should have a problem with effectiveness, especially with effectiveness of the systems and techniques that Government funding has produce. Why hasn't that been cranked into the development process itself?

Dr. ROBERTS. I think the answer lies in the system of incentives that we have been talking about.

From the point at which physicians are trained to the point at which administrators are paid, there is no incentive to produce, employ or be concerned about the cost as well as the effectiveness of new technology.

And, unless we begin to, in effect, redefine the physician's image of his or herself and also the system within which they work in a mutually complementary way, unless we work at both sides of the problem at the same time, as you suggested, I don't see that we are going to make much progress in this regard.

We have, in a sense, had too much incentive in the direction of the development of quality-enhancing technology, and too much incentive to diffuse it widely and not enough incentive to develop other kinds of technology. It's not technology "yes or no," it's what kinds of technology we have incurred.

Mr. SCHEUER. Just to be the devil's advocate, are you saying that we have too much quality in our health care?

Dr. ROBERTS. I think we have too much investment in technology that may, in fact, have some small benefit, but which is not worth the cost.

And I think we have to be willing to face that.

Mr. SCHEUER. And how do you tell when a technique is cost-effective; what are the criteria, and who is to make that judgment? I would be happy if you and I could make all those judgments, but the problem is that other people are going to get into the act, and I don't trust them.

How do we rationalize the decisions so that we maximize the likelihood they're going to be made in the public interest—considering all those factors you have talked about, especially the very delicate possibility of consciously reducing the quality of care even in a miniscule fashion——

Dr. ROBERTS. I think you have put your hand on the most——

Mr. SCHEUER. My finger. We are shooting with a high-powered rifle with an 8-power scope.

Dr. ROBERTS. I'm sorry. Put your finger on one of the most difficult problems. It is clear that we cannot leave it to the physician, at the time of illness, to make that decision. We know that the incentives are wrong in that context.

Mr. SCHEUER. So how is the decision going to be made? We understand that we can't let the doctor make it by himself.

Dr. ROBERTS. I think as an experiment, the sort of mechanism you proposed; that is, on a national level we set some regional resource constraints, and we seek to rely either on the regular political process on a regional basis or on a specially designed quasi-political process.

We have processes we have created with regard to HSA's and PSRO's to try to balance competing interests. I am not persuaded that HSA's and PSRO's are the very model of Greek city/state democracy which will rise in splendor to this challenge, but it is not clear that we have any better alternative. And to the extent that we begin to rely on them to make important decisions, we strengthen everyone's stake in the process, and perhaps we will strenghten the agencies in a sort of sink-or-swim approach to their role.

I am convinced that we have to find some place where we tie both financing and quality concerns together in a single decision-making process. And since the financing side involves balancing the benefits to be obtained from using these resources in the medical area against the benefits to be obtained by using these resources somewhere else, doctors and providers have an important role to play, but they certainly don't have a monoply of the relevant expertise in social judgment.

Mr. SCHEUER. So you are talking about some kind of regional caps.

Dr. ROBERTS. Part of the difficulty with that approach is illustrated by experience in Toronto with institutional caps.

One of the things that happens, as you start influencing the flow of funds to different sectors of the system, is that you encourage the bureaucratic realinement of different fragments of the system into different units in order to maximize revenue.

For example, one of the things that happened in the Canadian case where they put revenue caps on the hospitals is that they virtually dissolved many laboratory services. They set their laboratories up as independent corporations, who then billed the patients independently. And the revenues of the laboratories were then exempt from revenue limits placed on the institution.

In any scheme one would have these administrative difficulties. Their existence is not an objection to pursuing the route, it's just that the more complicated the scheme, the more likely we are to create perverse incentives of the sort we would like to be rid of. We have already noted certain perverse incentives of that sort. We have a tendency to hospitalize people for things that could be done in an outpatient way because the system pays more for certain procedures on an inpatient than on an outpatent basis. We don't want to inadvertently create any more such distortions.

Mr. SCHEUER. You hospitalize them on Friday and give them their first look at a doctor on Monday.

Dr. ROBERTS. I guess I am persuaded that we ought to try to allow regions to make some of these decisions in the broad-strategy questions. I am in some ways more concerned about the allocation of resources within given institutions.

One of the things we have seen as a result of the pressure that Congress has already put on the system and the cost-containment

pressures we face, is substantial internal evolution in the manner of construction of additional hospital space.

Hospitals used to live in a very generous environment, in which the solution to any resource allocation problem, where A said he wanted this and B said he wanted that, was to give both A and B what they wanted. Now, rate-setting process and certificate of need processes make that no longer possible in many cases.

We have had a general shift of authority within the hospital away from the individual chiefs of clinical services to the central administration. We have a rise in the need for adequate and modern budgeting and cost-accounting procedures. We still have a long way to go, but we are moving in that direction.

In effect, we have increased the hospitals' capacity internally to allocate resources in a way that reflects some coherent vision of the institution's long-run perspective, as opposed to just the pieces of individual fiefdoms within it. I think we have to find ways to strengthen the central allocation processes within hospitals in order to further improve their capacity to respond to the pressures that we are going to put on them.

Dr. WELLS. Dr. Roberts, analogously in other areas, the Federal Government does take action to exert long-term effects on the mix of people and other resources within the scientific community.

For example, by its allocation of funds between astronomy, physics, chemistry, the National Science Foundation has the effect of influencing the number of people in the field over, say, a decade of time. For example, since the field of astronomy has become saturated, it is no longer making significant contributions for astronomers. As you pointed out earlier, if you want to go into astronomy now, you go into debt. You don't get post-doctoral fellowships.

It appears from yours and other testimonies that the development of increasing specialization leads to further pressures on the developing of special technologies which are expensive if nothing else.

Is there a Federal role here to try to influence the structure of the medical profession in terms of specially training in the schools?

Dr. ROBERTS. Well, Dr. Wells, as you know, the Federal Government has already begun to take that role in the current provisions for financing medical schools and the requirements on first-year residency programs in primary and nonprimary care. So the Government has begun to try to make its influence felt.

I think that any effort that the Federal Government makes in this area should be chosen as an incentive as opposed to regulatory approach. I would be, myself, much more comfortable with the Federal financing role for postgraduate medical education in the sort of situation you described in astronomy.

We're not telling them "you can't go into astronomy". We are not closing down any departments of astronomy. We are simply saying "we are not going to pay for it, and if you can find someone else to pay for it, go forth and multiply—do your thing."

I think that is a much less coercive role than regulatory mechanisms which, in a sense, limit people's opportunities much more.

If the howls of the teaching hospitals around efforts to move to prudent buyer-based reimbursement for medicare/medicaid can be heard in this room, then I venture to say that the howls of the

medical schools, if we seek to restrict further the patterns of speciality training, will be equally loud.

It seems to me that one needs to find the appropriate mode for influencing the private sector. We have found, for better or worse, that there are shifts in interests and perspective over time; and, given the cycle with which the Congress operates, I'm a little reluctant to rely entirely on the political process to respond to the shifting winds of the medical marketplace. And I would like to reserve more flexibility in the system than a straitjacket of specialty regulation might allow.

Mr. SCHEUER. The political marketplace may be willing to make some judgments, but there are other judgments that I am not sure it is capable of making.

Take the question of kidney dialysis. That, obviously, involves and almost explosive issues involving—what are some of the ways we can at least move the system toward home dialysis treatment?

Dr. ROBERTS. I think the critical question posed by the kidney dialysis issue is, the ability of the Congress to adequately face the trade-off between wishing to provide benefits and wishing to contain costs.

The extent to which the Congress has chosen to make kidney dialysis generally available is a source of several problems. Many thoughtful physicians I know question the overall social cost-effectiveness of that resource allocation decision.

It is not just that a physician faced with a patient has trouble saying "no". It's that Congress faced with a class of cases, they too have trouble saying "no".

Mr. SCHEUER. Where and how should those kinds of very hard decisions involving triage be made? Do you keep an 85-year-old individual alive at the cost of $20,000 or $30,000 a year when 30 or 40 percent of your people from birth to 60 have not had their inoculations for German measles or polio, where almost half of the kids who go to be inducted in the service have never seen a dentist? How do you make those agonizing decisions?

Dr. ROBERTS. I'm afraid I believe that there is no place for the broad-recourse allocation choices except in the hands of Congress. I mean, the Congress is the place where broad social priorities are supposed to be balanced. This is not a matter of technical expertise. This is a matter of social values. That's what legislatures are for; that's what Madison said they were for in the Federalist 10. And if the Congress fails us, I don't think we can look anywhere else.

I think that we have to face the individual doctor in the individual regional system with resource limits that are provided on a national basis and let him optimize—to use the jargon "optimize"—within those constraints.

But the constraints you proposed earlier, the broad embodiment of social policy and basic resource choices, has to come from the Congress. And it means, to some extent, we have to find a way of posing those issues appropriately to the Congress and resolving them.

Mr. SCHEUER. Dr. Roberts, we have gone way, way over our time with you, and it is obvious that you have challenged us and stimulated us, and we thank you very much.

Dr. ROBERTS. Thank you very much, Mr. Chairman.

Mr. SCHEUER. We will now hear from Andrew W. Miller, senior vice president for administration, Hospital Corp. of America.

We are delighted to have you with us, Mr. Miller.

Your statement will be printed at this point in the hearing in its entirety. So you might want to just chat informally with us for 10 or 15 minutes; hit on the highlights of your statement, perhaps referring to anything that you have heard here this morning. Then after that, I'm sure we will have some questions.

[Prepared statement of Andrew W. Miller, senior vice president for administration, Hospital Corp. of America is as follows:]

HOUSE SCIENCE AND TECHNOLOGY SUBCOMMITTEE ON
DOMESTIC AND INTERNATIONAL
SCIENTIFIC PLANNING, ANALYSIS, AND COOPERATION

Statement of

ANDREW W. MILLER
Senior Vice President
Hospital Corporation of America
Nashville, Tennessee
and
President
Federation of American Hospitals

September 26, 1978

Mr. Chairman, members of the Subcommittee, I am Andrew W. Miller, Senior Vice President of Hospital Corporation of America, a Tennessee headquartered hospital management company. I am also honored to serve this year as the President of the Federation of American Hospitals, a Washington based non-profit association which represents more than 1,000 investor-owned hospitals nationwide.

I am very grateful for the invitation to testify before your Subcommittee, and I commend you for your interest in the important subject of technology and the cost of health care.

HCA is a company dedicated to the delivery of high quality health care and the utlization and development of sound business principles for the management of health care delivery. We also develop and construct hospital projects for other owners, sell hospital equipment and supplies to major foreign hospitals, provide professional health care recruiting of physicians and allied health personnel for hospitals throughout the world and conduct international health care research and feasibility studies for foreign governments, agencies and private institutions.

The Federation of American Hospitals (FAH), as the responsible information source on vital industry issues, is

identified with containing escalating hospital costs, assuring quality of health care and patient satisfaction, and explaining the effects of state rate regulation. Its authority in the hospital community is also felt in the areas of management contracts, expansion by investor-owned hospital companies into foreign markets, and health care legislation.

Both HCA and the FAH share the concern of many people for the most appropriate development and deployment of health technology. The work of your Subcommittee can have a highly constructive and stimulating effect on the health sciences and the effective expenditure of public funds for health care.

The biomedical science effort of the United States has earned worldwide respect. The health benefits which have been extended to millions of people throughout the world are a tribute to the National Institutes of Health, the Public Health Service, the Veteran's Administration and the Department of Health, Education, and Welfare and the many public and private groups which have made so many advances in health care possible.

It is timely that we now have growing concerns about finding ways in which the social utility of this great

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effort can be further enhanced. This occurs at a time when technology's reign as the primary shaper of medical progress is being strongly questioned. The shift in attitude is largely conditoned by the recognition that the diffusion of technology throughout the health care system, and particularly in hospitals, constitutes a major reason for rapidly rising health care costs. Dr. Richard H. Egdahl of Boston University Medical Center states in the August 31, 1978, issue of "The New England Journal of Medicine" that the development and application of new technology accounts for an additional five to ten percent of costs above the national rate of inflation. As more and more of the nation's resources are being committed to the financing of health care, particularly by the government, there has been more and more questioning of technology's impact, not only in terms of the drain on financial resources but also in terms of the outcome on the nation's health status and the risks to patients and society.

Changes in medical care organization, brought about in part by technological advancement, have had important effects on the industry's values and goals. Since World War II, there has been an accelerating trend toward more institutionalized health care. In the U.S., medical care organization includes not only the traditional forms of private fee-for-service medicine but the type practiced in the "medical

center" -- at whose heart lie the medical school and the university teaching hospital. Radiating from the center is typically a complex network of referring physicians and clinics, which are usually linked to the medical school by medical education programs.

Medical care in the medical center utilizes the skills of a variety of specialists and sub-specialists, as well as the most advanced medical technology. In the academic setting of the teaching hospital, quality of care is looked upon as a function of technical proficiency -- the application of the latest advances in medical technology. In this regard, the university sets the standards for the rest of the industry. Criteria for quality of care can be affected by overspecialization, since they are often technologically derived rather than defined on the basis of the needs of the patient. Technical proficiency is often the measure of the organizational performance.

When the interests of physicians combine with the goal of technical proficiency, the result is pressure for physical plant expansion and the acquisition of services both of which commonly are viewed as indicators of medical center performance.

To summarize, advances in medical technology have a tremendous impact on the health industry's values and goals, to

the point that technology continues to shape both the organization of the health care system, and the physician's pattern of delivering services.

I caution against a rapid alteration in the health care system's performance resulting from the implementation of regulations which control the development, utilization and phase-out of medical technology. This is particularly important to consider in light of the impact that medical technology has upon the organizational structure and patterns of providing services within the health care system. Regulatory actions, without adequate information from the technology assessment process, which the Office of Technology Assessment asserts is limited in its ability to predict the impact of specific technologies upon the health care system, may actually lower the level of effectiveness, quality, and efficiency within the system.

The significant advances in medicine have dramatically increased total health care costs. Harry Nelson of the Los Angeles Times wrote in an article published July 21, 1977, that:

> "Doctor and hospital costs for a bone marrow transplant at UCLA are $50,000 and up."

"A whole body scanner requires an initial outlay of about $500,000, plus about $300,000 a year to operate."

"Intravenous hyperalimentation, a method of feeding nutrionally deficient cancer patients, may cost $500 a day."

"A recent case of hyaline membrane disease in a premature infant cost the California Crippled Children's Services Program $200,000."

"In 1976, the Medicare program spent $450 million for dialyzing the kidneys of 18,000 patients. Within five years the dialysis program is expected to cost $1 billion annually."

"These are among the scores of examples of health care costs which only a few years ago would not have existed, because the technological wherewithal to accomplish the treatments did not exist." Furthermore, the public's expectations of what medicine is capable of doing have risen greatly as a result of "medical miracles."

These expectations of medical science have been a major source for the expansion of health care services and the resulting inflation. Health care providers now provide far more sophisticated care than 20 years ago. The intense development of diagnostic, surgical, and therapeutic technology which physicians can now call on to relieve illnesses that previously were untreatable, and the fact that the majority of patients have health insurance and are

willing to pay for these services, have resulted in a very extensive deployment of health technology, particularly in the United States. Improved diagnostic, surgical, radiation, and chemotherapy equipment and techniques enable many forms of cancer to be detected earlier, and some patients to be cured or allowed to have longer remissions. Pacemakers and heart bypass surgery have added productive years to cardiac victims; as have hip replacements for arthritis patients.

Unlike technology in other industries, which usually has the effect of reducing manpower and production costs, many of the new technologies in the health care field cause increased capital and labor costs. This change reflects a shift away from technologies that were relatively equipment free (e.g. drugs) in which costs are incurred primarily in research, development and marketing efforts; to technologies that are equipment intensive, in which costs are incurred through required hospitalization of patients as exemplified by open heart surgery. Using AHA statistics, Gaus and Cooper have shown in their paper on "Technology and Medicine: Alternatives for Change," presented to the Conference on Health Care Technology at Boston University in 1976, that the expense per patient day in community hospitals rose from $49 to $147 between 1967 and 1976. The technology factor, reflecting this change in intensity, represented 47.3 percent of the nine year increase of $98 per patient day. Furthermore,

as medical equipment and procedures become more complex, the life cycle of the technology often becomes shorter as new advances are stimulated and achieved. Advances in technology also often generate the need for greater specialization by doctors, nurses, and technicians. This results in more training programs, teachers, and program directors to orientate these professional resources and keep them abreast of new methods and techniques.

Health technology is important to assess from the perspective of the breadth of its impact. Its impact includes: the quality of care; inflation, productivity, and costs; health care and the disadvantaged; health manpower; health insurance; planning and regulation; ambulatory care and emergency medical services; long term care; mental health; rehabilitation; early disease diagnosis; specific disease prevention; curative therapy; and preventive health maintenance. As one can readily determine, virtually every major facet of health care will be affected by the development of new technology and decisions relating to its utilization.

I recognize that a subject of this hearing is the development of the new Office of Health Technology under the Assistant Secretary of Health which was recently established by the Secretary of HEW. The multi-agency survey team was created by the distinguished Assistant Secretary of Health,

Dr. Julius Richmond, and the Assistant Secretary of Planning & Evaluation, Mr. Henry Aaron, approximately one year ago. The team surveyed the technology-based activities which are taking place in HEW, to identify the gaps and deficiencies in those activities, and to outline a strategy to cope with the cited deficiencies, and as a result produced a very sobering report in late December of 1977, on Health Technology Management at HEW.

As Dr. Richmond commented in his own testimony before the Senate Subcommitte on Health & Scientific Affairs on February 7, relative to S. 2466, and I quote:

> "Our study has....made us keenly aware that while the Department is extensively involved with technology as a developer, an evaluator, a purchaser, and a regulator, it has no comprehensive strategy to systematically link stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization and phase-out."

The technology management strategy which emerged from the study consists of the following major sequences:

1. Identification and screening of candidate technologies and health needs for analysis.

2. Annual priority setting for Departmental study agenda.

3. Conduct or sponsorship of studies.

4. "Translation" and synthesis of technical findings.

5. Explicit decision making to restrain or stimulate development and use of a target technology.

6. Implementation of decisions through a spectrum of such intervention mechanisms as allocation of R & D resources, market approval, incentives, utilization guidelines, and professional and consumer education.

This technology management strategy, with certain reservations, in particular concerning the use of restraint in the development or dissemination of technology, presents in my opinion, a constructive first step to more effectively address this important area of health policy.

As a provider, a consumer, and a tax payer, I feel that it is vitally important to resolve many of the deficiencies cited in the report. The absence of a catalog of existing, new, and developing technologies; of a systematized approach to identifying and screening technologies to be studied with public funds; the lack of assurance of agencies' focus on national health priority needs (and the determination of such priorities); the absence of cost-benefit and cost-effectiveness studies; the ineffective lingage between study findings and agency actions; limited information dissemination regarding technology studies and the effects they have on allocation of publicly funded R & D;

is no longer acceptable. A more strategically based process must be developed to effectively allocate public funds for future health care services.

The intentions expressed in the report and the previously cited testimony of Dr. Richmond to annually select a small number of high-priority technologies, through a broad based participatory process, and subject them to a rigorous evaluation has the potential to effectively condition the critically important assessment process and management strategy development with respect to the very difficult issues of evaluation, decision making, and intervention.

I would caution those associated with the development of the Office of Health Technology to recognize that the current state of the art of analysis and testing techniques will often pose barriers to obtaining definitive answers to many questions. Research pertaining to the application of technology involves complex biological, behavioral, statistical, epidemiological, and ethical considerations. Questions pertaining to the potential future consequences of new or emerging technologies on society, the economy, the physical environment, the law, institutions, mores, and ethics will be particularly difficult. We must recognize that medical technology is constantly changing and generally accepted methods for cost-effectiveness analysis of new clinical procedures do not exist.

Furthermore, although technology assessment is important and promising as a method of predicting and dealing with societal impacts of technology, there are problems in applying technology assessment in practice. Quoting a report by the Office of Technology Assessment, reported in 1976, the following limitations were indicated:

1. The field is still a new one. There is no standard, widely agreed upon method for performing technology assessment.

2. Medical technologies are diverse and have complicated patterns of development. Therefore, it is uncertain that there will ever be a standard format for assessing medical technologies.

3. Technology assessments are hampered by weaknesses in the tools and techniques of social science that must be used to calculate social impacts.

4. Groups carrying out technology assessments have had great difficulty establishing boundaries for their studies.

5. Study groups have had difficulty achieving profitable cooperation and communication among experts from different disciplines working on research teams.

6. V. E. Coates of George Washington University, in a study prepared for the National Science Foundation, indicates that the average cost of comprehensive technology assessments was $381,000, with an average elapsed time of 16 months. This investment automatically limits the use of technology assessment to particularly troubling problems or technologies.

In the final analysis, HEW staff will have to weigh uncertain evidence of scientific inquiry against their best

estimates of the value of the quality of life and costs. This has significant implications for the quality of staff which will need to be attracted to such responsible positions and the oversight which the Health Care Technology Advisory Committee, proposed in H.R. 12584, will need to give to this important work. It is imperative that the quality of life vis-a-vis one's health be given a very high priority.

To support this effort, the Office will need a number of high-quality scientists qualified to tackle these difficult problems and an ability to collaborate across disciplinary lines. It will furthermore require first class leadership.

As the Final Phase I Report for the Secretary on Health Technology Management at HEW mentions, there will need to be a visible and predictable decision making process which can convert the weight of technical information and expert opinion into broadly coordinated interventions which affect the generation, adoption, diffusion, or phase-out of technologies. It is my feeling that this should be closely integrated with the work of the Committee.

The Health Care Technology Advisory Committee provided for in H.R. 12584, is an essential component to the effective development of generally supported priorities for research, demonstrations, and evaluations of medical technologies

concerning the safety, efficacy, effectiveness, and cost efficiencies, as well as the social, ethical, and economic impacts of particular technologies. The annual preparation of a technology analysis agenda, as recommended in the Final Phase I Report for the Secretary on Health Technology Management at HEW, should include the active review, input, and ideally, the approval of the Committee. Programs developed for cost-benefit and cost-effectiveness analyses and comprehensive technology assessment should also be subject to the review of the Council. The Committee should have a genuine role in determining the analysis and testing, review and synthesis, decision making, and intervention mechanisms provided for in the report.

To obtain the favorable and essential support of providers, it is critically important that the composition of the Committee include practicing hospital administrators in addition to practicing physicians, leading medical and scientific authorities, economists, attorneys, and outstanding people selected from the general public. In failing to include a practicing hospital administrator with vital knowledge and expertise of the single largest component of the health industry -- the hospital, the Committee would weaken both its base of support and its credibility. Indeed, the absence of a single hospital provider on the National Council on Health Planning and Development is felt by many health

care people to be inappropriate and sharply contrary to the significant teamwork which is so desirable if public programs are to receive the understanding and support of the private sector, necessary to the success of valid public initiatives.

The economics of the health care system represent vitally important considerations for the effective deployment of health technology. The current health system lacks workable incentives for economy. For example, the pressure to attract and retain physicians often forces hospitals to provide the latest, most technologically advanced diagnostic and treatment equipment. In many situations, the demand for the equipment may not be sufficient to insure optimal utilization. Yet, the cost reimbursement mechanism eliminates the risk of loss by fully covering excessive cost. To curb unnecessary proliferation of technology, I would caution against relying on a prevasive regulatory system. Instead, the Congress should redesign its method of paying for health care, so that efficiency is rewarded and mismanagement penalized.

Cost reimbursement mechanisms under Medicare, Medicaid, and many Blue Cross Plans are the prevailing methods of third party payment. Such mechanisms are inherently inflationary in that they fail to provide incentives for efficiency in hospital performance. Indeed, I know of nothing that

violates every principle of economics considered vital to efficient operations more completely than these forms of reimbursement. They are almost totally counter productive in their influences on management decisions. For example, patients through their physicians have every right under these reimbursement programs to demand and receive the best and latest in equipment and services. Even in situations where the cost per unit of service is twice, or for that matter 100 times higher than appropriate, hospitals are often financially encouraged to duplicate facilities, build excess beds, and add the latest in technology.

Reimbursement based upon negotiated rates is a method of paying hospitals in which amounts or rates of payment are prospectively established and understood by both the hospitals and third party payors. The hospitals are paid these amounts or rates regardless of the costs they actually incur. This financial structure forces management to focus on performance by rewarding the hospital if costs are below the rate or penalize the hospital if costs are above the given rate. This form of reimbursement thereby shifts the risk for cost from third party payors to hospitals, in contrast to cost reimbursement mechanisms under Medicare, Medicaid, and Blue Cross, where payors assume substantially all of the risks for whatever hospitals spend.

I agree with certain observations made recently by William L. Dowling, Ph.D., Director of The Graduate Program in Health Services and Planning at the University of Washington. Dr. Dowling noted the following positive incentives as being exhibited by a rate-based reimbursement program:

1. Hospitals would be motivated to anticipate and justify future expenditures and to establish the need for new facilities and services in attempting to gain recognition of the cost of their plans in their prospective rates. This would lead to greater cost consciousness in capital and operations planning.

2. Hospitals would be more motivated to identify and monitor the cost implications of the quantity, quality, and the scope of services they provide to assure themselves that they can operate within their rates. This could lead to improved forecasting, budgeting, cost-finding, and cost control techniques.

3. Hospitals would furthermore be motivated to keep their actual costs below their rates to avoid losses or to achieve surpluses. This should lead to more effective and efficient operations.

The central issue is not the timing of payment allocations, be they retrospective or prospective in nature, but one of assessing the base of payment and the incentives associated with each.

I therefore urge the Subcommittee to support action to modify the counter-productive cost reimbursement methodology of the Medicare and Medicaid programs, which have enabled the rapid expansion of new bed capacities and the rapid diffusion of new technology and services, by implementing incentive provisions to place providers at risk.

The intervention mechanisms identified in the Final Phase I Report for the Secretary to stimulate or impede development, utilization and phase-out of medical technologies, present a wide array of policy alternatives. The regulatory mechanisms which are already in place such as required FDA approval, certificate of need/Section 1122, health planning guidelines, professional standards review and reimbursement have in most cases demonstrated important progress and/or capacity to deal with their respective areas of regulation. Local responsibility for many of these activities, will, however, continue to be imperative to sustain reasonable acceptance by providers and the American people.

Market incentives such as development subsidies, tax subsidies and market aggregation deserve further consideration and experimentation. They can be significant factors in stimulating desired development of technology and production. Positive incentives present important opportunities to achieve cooperation from the private sector that meets the public interest and would preclude an extensive regulatory structure.

I would be less than candid if I did not express serious reservations about the wisdom of centralizing potentially tremendous power in the hands of a few; far removed from the local needs of patient-physician relationships, hospitals, Professional Standards Review Organizations, and decentralized health planning agencies. Federal employees who write and administer the regulations over health technology should not have almost unchallengable power in their specialized areas. Too often such people perceive regulation as an end in itself. When regulators become impervious to reasonable influence on the question of what is workable, if not broadly acceptable, they become essentially uncontrolled. The situation becomes worse if the Department of HEW takes a posture of trying anything to reduce health care expenditures. In the absense of widely supported standards, such regulation will tend to operate with a clear and unacceptable conflict of interest, especially when the federal government continues to operate at enormous deficits despite regulatory attempts.

While the Office will apparently be given advisory powers only, it does not require great imagination to perceive the eventual requirement for approval as a condition precedent to reimbursement under Medicare and Medicaid. It is reasonable to perceive that the next step would require the issuance of "guidelines" on health technology which would be for the purpose of infulencing the action of health systems agencies and State health planning and development agencies. Within

a few years, the Office of Health Technology could be the FDA of the health technology industry, subjecting every new innovation not only to an efficacy requirement but to cost effectiveness, ethical suitability, and social desirability requirements as well. I hope that it will not evolve into a quasi-judicial, regulatory body nor become a major stepping stone to the centrally planned and controlled national health care delivery system in the U.S. advocated by some people.

My concerns are also conditioned by knowledge that one component of the cost of federal regulation - the cost of operating federal regulatory agencies - is expected to more than double in the fiscal years 1974 - 79, rising more rapidly than the population of the country or the gross national product. Far larger and more difficult to determine is the less recognized component of regulatory costs - the compliance costs. These include not only the direct costs that businesses incur in complying with federal mandates but also the indirect costs that arise when these mandates intrude on the efficiency of markets. Murray Weidenbaum, Director of the Center for the Study of American Business at Washington University, St. Louis, projects that for fiscal year 1979, the sum of administrative costs of federal regulation, paid by the taxpayer, and the compliance costs, generally passed on to the consumer in the form of higher prices, may top $100 billion.

It is also important to note the findings of a 1978 report

on the Cost of Regulation as published by the Hospital Association of New York State. This study focuses on the cost of complying with both federal and state regulations by hospitals in New York State. The findings are:

1. Twenty-five percent of hospital costs are attributable to meeting government regulatory requirements.

2. The annual cost to hospitals and the patients they serve is in excess of $1.1 billion.

3. About 115 million man-hours per year are needed to meet regulatory requirements.

4. The annual commitment of 115 million man-hours to regulatory matters is the equivalent of more than 56,000 hospital employees spending all of their time on regulatory matters. This is enough people to staff 75 hospitals, each with an average of 250 beds. Further, 56,000 hospital personnel could provide medical services to approximately 600,000 hospital patients.

5. About 24% of all man-hours are spent on regulatory matters.

6. Registered Professional Nurses, traditionally considered to be totally involved in patient care, spend 25% of their time on regulatory matters.

7. Regulated hospital functions, such as extensive record-keeping, consume 64% of the total regulatory cost.

8. Forms and reports required by the regulators are estimated to cost more than $128 million annually.

9. Four hospital departments--Administration, Personnel, Social Services and Utilization Review--each devotes in excess of 50% of their costs to meeting regulatory requirements.

10. The cost of new hospital regulations is estimated to be 4% more each year.

To summarize, the health industry is subjected to an increasing number of regulations in spite of questionable cost reductions. Indeed, such findings,as presented in the preceeding report,suggest that regulatory activities may require compliance activity which contributes far more to the hospital cost problem than to its solution.

In order to comply with the various aspects of expanding regulatory requirements, manufacturers of medical technology will face significant delays between capital investments for research and the development of new equipment and capital recovery when the equipment is marketed. As a result, the cost of new technology in terms of health care related equipment, drugs and medical supplies will continue to increase due to the high cost of development and the lengthly approval process that a manufacturer must undergo to obtain approvals from regulatory bodies.

As a case in point, Bell Labs points to the requirements of the Food and Drug Administration. According to one study, a 1938 application of adrenaline in oil was presented to the FDA in 27 pages. In 1958, the treatment for pin worms took 439 pages to describe. By 1972, a skeletal muscle relaxant involved 456 volumes, each two inches thick -- 78 feet in total thickness and weighing one ton.

Manufacturers may not be able to go into mass production

with newly developed equipment, even with federal approval, since the projection of hospitals capable of obtaining a certificate of need may well be unknown. This will undoubtedly cause higher technology costs through longer development time and potentially more limited production. In addition, risks associated with potential non-approval of research and development projects involving large investments will result in considerable disincentives for companies manufacturing medical technology.

The federal government, by controlling the development and utilization of medical technology, under the thrust of cost containment, is not only making a decision about the quality of services provided an isolated patient, but is making a decision about the quality of services available to the community in the future. Regardless of justification, regulation will continue to increase the cost of new technology to the hospitals in the future.

The result of increased regulatory intervention in the private market will undoubtedly be:

1. A reduced level of innovation in medical technology due to increased cost and high levels of risk;

2. Delays in bringing improvements in medical technology to the patient's bedside, and;

3. The centralized process incorporated by medical technology assessment may lower the quality of health care available to the American public.

Indeed, it is unclear if the benefits provided by the process of technology assessment will be greater than the administrative and compliance cost generated by the process. Cost-benefit analysis of the "technology assessment" process is certainly in order prior to the implementation of policy decisions.

I urge you to consider wherever possible, a decentralized process incorporating the existing Health System Agency and PSRO networks which are able to receive local inputs and evaluate the allocation of resources to meet local needs. I believe that the role of the federal government must be one of coordination by providing the framework and guidelines for local control and not one of further encroachment upon local determination and the free enterprise system via increasingly centralized regulatory requirements.

At Hospital Corporation of America, we purchased approximately $71 million in equipment during 1977 to replace outmoded equipment, provide needed new patient services and equip new hospitals. Similar I am sure to the practice of other large, investor owned hospital companies, we make a point to keep abreast of new technologies applicable to hospitals. Close

communication with suppliers, their product research groups, physicians and others allows us to carefully follow developments of particular significance. Improvements in diagnosis and treatment and more cost effective supplies and equipment are of high interest. Rather than indiscriminately purchasing new products upon their market entry, we carefully evaluate them over time with the assistance of leading physicians, other health professionals and appropriate hospital administrative staff members. The scrutiny focuses on the acceptance of the product, its impact on the quality and cost of patient care, product safety, maintenance and quality of the product. Often information is sought from recognized independent research institutes to provide further depth and objectivity to our analysis. The potential sharing of information from the Office of Health Technology would be a valuable addition to the information base we desire.

The encouragement of innovation which can result in new economies of scale or methods of deploying advanced technology more economically is also an important benefit that, hopefully, can be stimulated and benefited by the new Office of Health Technology. To illustrate my point - much criticism has been directed against the increase in health care costs resulting from the purchase and utilization of expensisve new technology. No recent technological development has been subjected to more of this criticism than the C.A.T. Scanner. The diagnostic achievements of computerized axial tomography have been dramatic

and are indisputable. This technology has frequently prevented the need for more costly surgical procedures. The critics of this new technology, as well as most health professionals and administrators, agree that it is not necessary for every hospital to have their own C.A.T. Scanner.

In an effort to address the problem of not requiring each hospital to purchase their own C.A.T. Scanner, but still have the service available, one of the major multi-hospital corporations designed a mobile van and installed a C.A.T. Scanner in it. As a result, many hospitals within a community can share both the benefits and the costs of the C.A.T. Scanner. This service keeps hospital costs to a minimum by relieving the hospital of dollars spent on the purchase of capital equipment or lease payments, technologist salaries, remodeling costs or patient transportation costs. All a hospital supplies is electricity, a parking area adjacent to the building, and a radiologist. Each vehicle serves a minimum of 4 - 8 hospitals within a specified area. Depending on the hospitals needs, it can receive services each day, or several days a week. At present, there are at least 5 of these units in operation. The hospital is billed a fixed fee for each scan done.

In February, the Medicare Bureau instructed its intermediaries to terminate reimbursement for mobile scanners. Their decision was based upon the interim response to a request of the Public Health Service as to whether the mobile scanners

should be reimbursed. The Public Health Service understandably suggested that Medicare suspend payment for mobile scans until they were able to determine whether there were any safety and efficacy problems as a result of the scanner being mobile rather than permanently installed.

Following their review, the Public Health Service recommended in June that mobile scans be reimbursed when scanners are installed according to manufacturer's specifications and meet F.D.A. diagnostic radiology performance standards applicable in fixed installations. In addition, they recommended that the scanner providers get appropriate approval from the respective health systems agencies. The Health Care Financing Administration as to date has not made a policy decision on their reimbursement.

This innovative mode of delivery was developed to allow hospitals to make this significant diagnostic service available for their patients. Further, this service was developed to allow hospitals to receive the advantage of this new technology without duplicating large investments in capital and operating costs, consistent with the needs of both the providers and local planning agencies. Yet, despite numerous meetings with HEW, the Department has not moved expeditiously to establish seemingly prudent reimbursement for mobile scans under Medicare and Medicaid. Such inconsistency on the behalf of HEW to support innovative services which aid in containing cost, results in

disincentives for the future development of innovative, cost efficient technology.

Congress has heard considerable testimony in recent months concerning the need to identify the gaps and deficiencies in health technology-based activities occurring in the various federal agencies and the need to better manage the investment of public funds as a developer, evaluator, purchaser and regulator of technology as it is applied to health care. It is necessary to determine in a more coordinated and effective manner major priorities for technology development, as well as desirable guidelines for the deployment of efficacious and safe technology which is considered to be cost effective relative to federal sponsorship.

Mr. Chairman, such existing health agencies as the distinguished National Institute of Health, the Center for Disease Control, the Food and Drug Administration, the National Center for Health Statistics, and the National Center for Health Services Research, among others, deserve vigorous support for their traditional missions. The new Office of Health Technology also deserves the support of Congress if the American people are to derive the most effective and timely benefits of the work of the scientific and medical community, which they have so generously supported.

The broad based involvement of a number of people within

government and from among the private sector will be required to achieve the objectives set forth in the report on Health Technology Management at HEW and the technology management strategy which was outlined by Dr. Richmond in February. I know that health care providers will be eager to participate at every level and will take their task very seriously. Medical schools will also need to be involved very heavily if the application and development of technology is to be more effectively shaped for the future. The role of the Office should be advisory and positive incentives should, in my opinion, be given the strongest possible emphasis for achieving the goals of this new public effort. Lastly, the development of the programs associated with this effort must give great weight to increasing the quality of health and health care services, to preserving the prudent prerogatives of physicians and strengthening the free enterprise system which has made so many of our American achievements possible. Thank you.

TESTIMONY OF ANDREW W. MILLER

Mr. MILLER. Mr. Chairman, I am senior vice president of Hospital Corp. of America, which is a Tennessee-headquartered management company operating some 110 hospitals with over 17,000 beds across the United States.

I am also honored to serve this year as president of the Federation of American Hospitals which is a Washington-based nonprofit association that represents more than 1,000 investor-owned hospitals nationwide.

With me is Mr. John Blount, who is an administrative resident of the Medical College of Virginia, participating in an education program with the Hospital Corp. of America.

We are very grateful for this invitation to testify before your subcommittee, and want to commend you for your interest in the important subject of technology and the cost of health care.

HCA is a company that is dedicated to the delivery of high quality health care and the utilization and development of sound business principles for the management of health care delivery.

We also develop and construct hospital projects for the owners, sell hospital equipment and supplies to major foreign hospitals, provide professional health care recruiting of physicians and allied health personnel for hospitals throughout the world and conduct international health care research and feasibility studies for foreign governments, agencies, and private institutions.

Both the HCA and the FAH share the concern of many people for the more appropriate development and deployment of health technology.

The work of your subcommittee, I think, can have a highly constructive and stimulating effect on the health sciences and the effective expenditures of public funds for health care.

To summarize, the points we want to make today are first, that technology is critically important to the very complex and diverse health care industry, impacting on its values and patterns of care.

Second, we would want to encourage and applaud the decision to create the Office of Health Technology and the use of positive incentive-oriented intervention measures such as tax preferential treatment, subsidy, or market aggregation concepts.

Mr. SCHEUER. Would you translate that into the English language?

Mr. MILLER. When Dr. Roberts was questioned about the point with respect to programs in astronomy and the educational field, he suggested that what should be done in this situation was the Federal Government or State governments providing funds. Offering incentives or not offering incentives, but not moving into a regulatory role with respect to education.

That is my point with respect to health care; I would like to see a role of positive intervention or nonintervention as opposed to regulatory——

Mr. SCHEUER. What is a positive nonintervention?

Mr. MILLER. Positive intervention or nonintervention; to intervene or not to intervene. That would be the decision, but not to regulate or disallow.

Mr. SCHEUER. I'm not sure—how do you distinguish between a positive intervention and regulation?

Mr. MILLER. You either allocate funds to stimulate the exploration of technology in a certain area, or you do not allocate funds to stimulate the development of that technology.

The regulatory approach would be to require all programs or expenditures to secure approval, such as with the FDA, before it——

Mr. SCHEUER. Were you here when the previous speaker testified?

Mr. MILLER. Yes, I was.

Mr. SCHEUER. He and I talked some about how to build in incentives for the development of technology, that would have as a purpose getting a handle on health costs, and also building in incentives for those people who are developing health care technology to maybe spend a little extra R. & D. money in trying to make them cost effective.

Right now there seems to be very little incentive to make health-care technology cost effective or in developing specific cost-control technology that has as its primary goal, cost control.

It seems to me that we have to build a system that is self-executing, that cannot rely on a grant here and a grant there to do a piddling little piece, as Lyndon Johnson would have said, of pissant research.

We have got to build incentives into the system so that hospitals and health technology manufacturers will want to look for the least expensive technology that is consistent with quality care, and that reflects concern for moderating and controlling the cost of health devices and systems.

Apart from the bandaid of a little grant here and a little grant there, how do we crank into this system incentive which would permeate the whole decisionmaking machinery with concerns for cost alone with the concern for health quality?

Mr. MILLER. One of the recommendations I wanted to present today in support is the recommendation for alternative provisions to the basic reimbursement system under medicare/medicaid programs.

These programs, as we discussed this morning, are retrospective cost-reimbursement programs and they encourage the dissemination of technology in marginally efficient situations. There is no doubt about it. They encourage the excessive construction of beds. They encourage excessive expenditures for technology because the cost—whether they are twice what they should be or 100 times what they should be in some cases are reimbursed under those programs, and those programs represent from 35 to 50 percent of a hospital's utilization. So, therefore, it is tremendously counterproductive in its influence.

The way I would suggest, and would want to propose, that something be done to revise the basic underlying, payment mechanism, is to place providers at risk by adopting a uniform rate system; do not pay hospitals based on what they spend, pay them what is reasonable, based on the services they provide.

That mechanism—and there's nothing unique about it, has been functioning in other industries. It has been the basis for the free enterprise system that has made this country what it is today. It encourages efficiency while placing providers at risk.

If in certain circumstances it's impossible for the provider to provide a high-technology service in a community, and the community wants that service, then allow the community to subsidize it.

But the basic correction factor should be focused on previously enacted legislation by the Congress, the medicare and medicaid programs.

Mr. SCHEUER. Please continue.

Mr. MILLER. The other point I would make is that the state of the art in health technology assessment is something we must carefully examine. Some of the numbers I have seen indicate that one assessment may cost as much as $400,000 and may take 16 months. That leads to concerns over the cost of health care regulation.

The costs of regulation are already staggering. I would suggest a cost-effectiveness evaluation of the function of technology assessment itself be performed.

The direct expenditures for compliance are staggering, but indirect costs including the lost-market opportunities, and other costs of intervention, are staggering, far beyond the direct costs.

I would also like to suggest that the potential misuse of power of an HEW Office of Technology Assessment is something we must always be concerned with.

The Department of Health, Education, and Welfare in its control of development and dissemination of technology might, under pressure for cost containment, allow such motivations to overshadow other considerations. That should be carefully weighed, in my opinion.

I would also like to note that the Health-Care Technology Advisory Committee, which is described in House bill 12584, includes provision for two hospital administrators. I think that is very important. The hospital is the major single segment of this industry, and the expertise that these individuals would be able to provide on such an advisory panel would be well worth the time and effort to include them there.

If I might, I will skip through some to the high spots of the written testimony.

The biomedical science effort of the United States has obviously earned worldwide respect. Health benefits have been extended to millions of people throughout the world, and these I attribute to the National Institutes of Health, the Public Health Service, the Veterans' Administration and the Department of Health, Education, and Welfare, and most importantly the system of private enterprise throughout this country.

It's timely, of course, that we now have growing concerns about finding ways in which the social utility of this great effort can be further enhanced.

This occurs at a time when technology's reign as the primary shaper of medical progress is being strongly questioned. This shift in attitude is largely conditioned by the recognition that the diffusion of technology throughout the health care system, and in particular in hospitals, constitutes a major reason for rapidly rising health care costs. Some numbers cited indicate that technology may be adding between 5 to 10 percentage points a year to the inflation rate in health care costs, and that is obviously of great concern. Also, advances in medical technology have had a tremen-

dous impact on the health industry's values and goals to the point that technology continues to shape both the organization of the health-care system and the physician's pattern of delivering services.

I would, therefore, caution against the rapid alteration in the health system's performance resulting from the implementation of regulations which control the development, utilization and phase-out of medical technology.

This is particularly important to consider in light of the impact that medical technology has upon the organizational structure and patterns of providing services throughout the health care system.

Regulatory actions, without adequate information from the technology assessment process, which, again, the Office of Technology Assessment asserts is limited in its ability to predict the impact of specific technologies upon the health care system, may actually lower the level of effectiveness, quality, and efficiency within the system.

Further, we're talking about 16 months for an assessment process during a period of double-digit inflation, or a very high inflation. Sixteen months' delay could be very significant.

There is a situation where one company within our industry has developed a mobile CT scanning unit, and has gone through a laborious process of getting this innovative idea approved by the Health Care Financing Administration. This cost-reducing equipment would be available to four to eight hospitals. They would be sharing the service, sharing the cost——

Mr. SCHEUER. Great idea.

Mr. MILLER. They have gone through tremendous problems in getting the mobile scanner approved for reimbursement under the medicare programs. Delays can stifle innovations.

Mr. SCHEUER. It seems to me they ought to grab it. It is such an obviously economical scheme.

Dr. WELLS. However, Mr. Chairman, Mr. Miller points out in his prepared statement that this was disallowed for a time under medicaid, and they are still waiting for HEW approval.

Mr. SCHEUER. Why was this——

Mr. MILLER. Clearance had not been given from the Public Health Service. The requirement was published that it must meet all the standards for a fixed unit in place. Once that was satisfied, then there was just no response after numerous meetings with HEW.

Mr. SCHEUER. It seems obvious that there must be a saving there. I would like to follow up and find out what seems to be holding that back.

Mr. MILLER. Thank you very much.

It I might continue, I would note that the subject of this hearing, as I understand it, is the development of the new Office of Health Technology under the Assistant Secretary of Health, recently established by the Secretary of HEW.

And this move was, at least in part, in response to the report of a multiagency survey team created by the distinguished Assistant Secretary of Health, Dr. Julius Richmond, and the Assistant Secretary of Planning and Evaluation, Mr. Henry Aaron, approximately 1 year ago.

The team surveyed the technology-based activities which are taking place in HEW, to identify the gaps and deficiencies in those activities, and to outline a strategy to cope with the cited deficiencies, and as a result produced a very sobering report in late December of 1977 on Health Technology Management at HEW.

Dr. Richmond commented in his own testimony recently, and I quote,

> Our study has made us keenly aware that while the Department is extensively involved with technology as a developer, and evaluator, a comprehensive strategy to systematically link stages in the life cycle of technology development, evaluation, transfer, diffusion, utilization, and phase-out does not exist.

Now, as a provider, as a consumer, and as a taxpayer, I feel that it is vitally important to resolve many of the deficiencies cited in the report. The absence of a catalog of existing, new, and developing technologies; of a systematized approach to identifying and screening technologies to be studied with public funds; the lack of assurance of agencies' focus on national health priority needs, and the determination of such priorities; the absence of cost-benefit and cost-effectiveness studies; the ineffective linkage between study findings and agency actions; limited information dissemination regarding technology studies and the effects they have on the allocation of publicly funded R. & D.; are simply no longer acceptable.

A more strategically based process must be developed to effectively allocate public funds for future health care services.

The intentions expressed in the report and the previously cited testimony of Dr. Richmond to annually select a small number of high-priority technologies, through a broad-based participatory process, and subject to them to a rigorous evaluation, has the potential to effectively condition the critically important assessment process and management strategy development with respect to the very difficult issues of evaluation, decisionmaking, and intervention.

I would, however, caution those associated with the development of the Office of Health Technology to recognize that the current state of the art of analysis and testing techniques would often pose barriers to obtaining definitive answers to many questions. Although technology assessment is important and promises a method of predicting and dealing with societal impact, there are problems in applying this assessment technique in practice.

In a report by the Congressional Office of Technology Assessment, the following limitation was indicated: The field is still a very new one, and there is no standard, widely agreed upon method for performing technology assessment.

In my submitted statement I cite four or five other points; the last one a quote by V. E. Coates of George Washington University. In a study prepared for the National Science Foundation, Coates indicates that the average cost of comprehensive technology assessments was $381,000 with an average elapsed time of 16 months. That was several years ago. This magnitude of investment automatically limits the use of technology assessment to particularly troubling problems or technologies. It cannot be used as a broad-based technique.

I would note that the Health Care Technology Advisory Committee provided for in H.R. 12584, is an essential component to the

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effective development of generally supported priorities for research demonstrations and evaluations of medical technologies concerning safety, efficacy, effectiveness, and cost efficiencies.

Mr. SCHEUER. That bill was passed yesterday.

Mr. MILLER. I understand that the Senate version does not include the two hospital administrators. I would certainly like to see those two administrators on that committee; and perhaps would like to take the opportunity to point out the fact that there is not now a hospital administrator on the National Planning Committee. That is something that has received a great deal of publicity recently.

Mr. SCHEUER. That is a mistake, and we will try and do what we can to see that in the conference process, the conferees in the House hold a particular position on that point.

Mr. MILLER. I'd like to get back, if I might, Mr. Chairman, to the point raised in response to your question about the health care system, and, if I might, on the vitally important considerations for the effective deployment of health technology.

Mr. SCHEUER. And I would like you to get specific, because you are providing some free private enterprise inputs here.

At present, the doctors are the ones who have the most power in the hospitals, and who have been traditionally involved in the decisionmaking affecting health costs in hospitals. But we are beginning to see a movement where administrators have some incentives and they're beginning to get a little power to affect these decisions.

Where should the balance be? Where should the power be between the doctor who wants the best and the most at whatever cost and the hospital administrator who is working with finite resources?

Mr. MILLER. From my vantage point in a for-profit hospital management company, I feel that we have a unique opportunity and a unique strength that we can bring to bear in this situation. We are able to relate to physicians. We include the physician as a member of the management team. We are able to effectively communicate return on investment requirements such that, before we expand funds for a service or a technology, there must be adequate demand to meet the ROE, return on equity, hurdle.

Mr. SCHEUER. What's ROE?

Mr. MILLER. Return on equity.

Mr. SCHEUER. We know that your firm is doing admirable work.

What we invited you here to testify about is, how do we apply your experience and your know-how into the system; how do we get cost-consciousness and the weighing of cost-effectiveness cranked into the system? Who is going to be making those hard decisions?

Now, I asked you a question about the balance between doctors and hospital administrators; how do we handle that crunch—you know, where does the buck stop?

Mr. MILLER. The buck stops with the hospital administrator. Our charge there is to present a rational program to the medical staff as to what new technology is justified in this situation, and to secure their concurrence with that. And because we're talking from the perspective of an investor-owned operation, those physicians understand that there must be adequate demand for the service,

given the market price that can be charged, for that service to carry itself, or to be appropriately justified. In other words, we're reminding them we are at risk, that there must be adequate demand for that service before we can install it.

Now, what can be generalized from that is the placing of all providers at risk. Then, there would have to be adequate demand before that service will carry itself, and there must be an adequate mechanism in place to insure that cross-subsidization is minimized.

Mr. SCHEUER. What do you meand by cross-subsidization?

Mr. MILLER. Increasing the rate for other services because the new CT scanner that you have added doesn't carry itself.

Mr. SCHEUER. Do you think that responsibility for making decisions on new technology should be placed on the hospital administrator; there should be a shift of power on that kind of decision from doctor to the administrator?

Mr. MILLER. That's right. And the administrator should be in the position of going to the local HSA and presenting his case for this new technology and, when it needs those things, getting the concurrence of the community with that recommendation.

Now, this ties back, Mr. Chairman, to the point we were making about the reimbursement mechanism. If you are reimbursing hospitals on cost, and expenditures under the medicare/medicaid programs are reimbursed regardless of the revenue generated, you are eliminating the risk.

If we could suggest that a going rate be established, based on community averages for what's reasonable, based on time and motion studies for what a CAT scan should cost, and it be a reasonably effective and efficient rate, then the hospital administrator, communicating with the medical staff would be able to say "our demand will not meet this need, therefore, financially we cannot afford to add this service unless we get a subsidy from some other source."

[Pause in proceedings.]

Mr. MILLER. I would not agree with the proposed cap approach. It's a gross oversimplification and would shock and abuse this industry. Anyway, I would disagree with some of the comments I heard earlier that "it would certainly be better than what we have, and, therefore, it is justified." I'm not sure that it would be better than what we have, and I don't agree with that approach.

Mr. SCHEUER. You don't believe in the cap approach?

Mr. MILLER. No, I don't. The cap approach would treat all hospitals alike. It would throw a substantial percentage of them to the mercy of whatever appeals mechanism was established to correct inequities.

It would be a tremendous bureaucratic problem.

The average hospital in Tennessee, is a community hospital with 150 beds, and they cannot live with that type of mechanism. They would be forced into real problems and have to throw themselves at the mercy of the appeals structure that would be created within the system.

Mr. SCHEUER. As I got Dr. Roberts' testimony, he would figure, or somebody would figure what the costs were for an appendectomy or a hysterectomy, or whatever the operation was, in a community hospital and then apply those costs to the tertiary hospitals.

I don't see the community hospitals getting hurt, because they have lower cost per service than the tertiary teaching hospitals.

What this would mean is, if we wanted teaching hospitals to continue their teaching function, we would have to pay them for performing that teaching function. We would not load the cost of teaching onto the cost of running the beds.

We would have to refine our thinking. And if society wants to train new doctors—which we obviously have to do—that has to be charged to medical education. At least we would know what we were paying for, and be making judgments on the realities and not just seeing the cost of operating hospital beds to into the stratosphere while we're sitting around helpless to begin to cope with the situation, because those costs were not composed of real health care costs.

They were to a significant extent composed of the cost of training the next generation of doctors. We will all face up to that, and exercise that element out of the hospital bed daily cost and look at it as a manpower training cost.

I don't see how, if this kind of thing were done, that small community hospitals would suffer at all. I think a cap would be based on the data that separates the different kinds of health services, and then tell the far more expensive hospitals, "shape up or ship out. If you have services that you want to perform that are not included in this menu, tell us about them and we will consider whether to fund them."

Mr. MILLER. Exactly. I certainly concur with those statements, observations, and that methodology.

Certainly, the recommendation that Dr. Roberts advanced with respect to the medicare and medicaid programs to pay on the basis of reasonable average cost for given services or procedures, and not the institution's actual cost, provides adequate cost-control incentives. I certainly concur. That's what I am trying to say.

Mr. SCHEUER. I think your testimony on page 17, items 1, 2, and 3 are in agreement with Dr. Roberts.

Mr. MILLER. Absolutely. If you read on to the next statement with respect to rate setting agencies, there were some points which would not allow automatic passthrough of capital investments.

And there were some points in earlier discussion in which you advanced the possibility of a cap approach on a statewide basis, or what-have-you, that I was responding to.

Mr. SCHEUER. You don't think that the cap approach on a statewide basis or regional basis would work?

Mr. MILLER. I do not. It's a matter of who gets there first.

Mr. SCHEUER. Well, it wouldn't quite be a matter of who gets there first, because everybody is going to be there trying to knock down the doors, and somebody is going to made some hard decisions about dividing up what is on the platter. It may be a question of who has more political muscle; the folks that make the decisions.

But I don't think that it would be a question of who gets there first. I think that somebody is going to have to look at the whole scheme from alpha to zed and make some very tough decisions: Do we provide the CAT scanner for a 95-year-old person, or do we try and give polio shots and German measle shots to the 34, 35, or 45 percent of the kids who don't get them, or do we try and provide

prenatal and postnatal care to a significant percentage of women who go to the hospital to give birth who have had no prenatal care. These are hard decisions.

Mr. MILLER. Yes, they are.

And as you noted this morning, I think that you and I could make them but I don't trust those people out there.

Referring again to the written testimony, on page 20 there is a recent study cited on the cost of regulation as published by the Hospital Association of New York State—pages 20 and 21.

This study focuses on the cost of complying with both Federal and State regulations by hospitals in New York State. These findings were, in part, that 25 percent of the hospital costs are attributable to meeting Government regulatory requirements. The annual cost to hospitals and the patients they serve is in excess of $1.1 billion. About 24 percent of all man-hours are spent on regulatory matters. Forms and reports required by the regulators are estimated to cost more than $128 million annually.

Three hospital departments, administration, personnel, and social services, each devotes in excess of 50 percent of their costs to meet regulatory requirements.

And, consistent with the point I made earlier, the cost of new hospital regulations is estimated to be 4 percent more each year.

Mr. SCHEUER. The cost of regulation is climbing at the rate of 4 percent a year?

Mr. MILLER. Yes, each year.

Mr. SCHEUER. How much was this burden of paper-pushing you cited—24 percent of all man-hours—I take it you mean man-hours of hospital administrators, or do you mean——

Mr. MILLER. Man-hours of the hospital.

Mr. SCHEUER. That's total health-care personnel?

Mr. MILLER. The total health-care personnel.

Mr. SCHEUER. It's almost an unbelievable figure, except I have heard something like it before. Computer experts told us that 20 to 25 percent of the cost allowances are devoted really to paper pushing.

Mr. MILLER. And meeting Government regulation requirements.

Mr. SCHEUER. What portion of that results from the fact that there are a number of different regulatory agencies who come in and want figures and data to fullfill their needs—so that hospitals have to keep three, four, or five, or six sets of books to fulfill the regulatory demands of Federal, State, and local agencies? What portion of this cost for regulation could be saved if we had some kind of a uniform accounting system, so that each hospital could have a quiet room with a computer sitting in the middle of it, and a comfortable lamp and a comfortable chair—and whatever regulatory body came into the hospital for data, they just usher the gentleman in and say, "be our guest," and that regulatory agent could push whatever buttons it wanted to and get whatever information it needed?

Did you understand the question I'm asking?

Mr. MILLER. Yes.

Mr. SCHEUER. Up at Massachusetts General Hospital the comptroller of that hospital complained to me of the hundreds of thousands of dollars that that one hospital was spending each year over

and above what it would have to spend if only the Government regulatory agencies could get their act together and require one set of data from which each agency could extract what it needed to fulfill its mandate.

This is why I ask you that question.

Mr. MILLER. There is tremendous cost—and I would be happy to provide you with some specific written information on this—detailing the cost resulting from duplicate reporting on requirements, and duplicate audits by different agencies.

Mr. SCHEUER. It's more than just duplicate audits. It is multiple audits by different agencies, each one of which required the hospital to uniquely prepare data for it in ways that are not required for the other regulatory agencies. So the hospitals have to go through enormous accounting expenses to tailor reports for each of these agencies, when they ought to be able to crank their operating data into a computer and tell the regulatory agencies, "here it is, ask the computer whatever you want and the computer will give you the answers."

Now, how much could that 24-percent figure—it has to shock any thinking individual—how much could that be reduced if we had this kind of a computer-based uniform hospital cost accounting system?

Mr. MILLER. My reaction to that, Mr. Chairman, is that that is somewhat utopian, and what is needed is a coordinated effort. A uniform reporting system will do nothing but layer on another burden. And perhaps over the next 10 years we might be able to get a few of the regulatory agencies to accept some of that data as part of their requirements, or to extract some of that data. I don't see uniform reporting currently being debated as a significant step in the right direction at all. I see it as just being——

Mr. SCHEUER. You're saying, in effect, the 24 percent is going stay at 24 percent, or go up at the rate of 4 percent a year?

Mr. MILLER. As a matter of fact, it may go up. As to the "Uniform Reporting Requirements," that's another 20 pages that would have to be reported in a medicare cost report to HEW that would probably get into some HEW computer somewhere, but as far as satisfying all the other needs, no.

There has been no coordinated effort, to my knowledge, to establish exactly what the data requirements were of the other agencies involved, and to meet those data requirements by this uniform reporting method.

Mr. SCHEUER. You're saying that not only has it not happened, but you're saying that it wouldn't be worthwhile for it to happen.

Mr. MILLER. I don't think it's possible for it to happen.

I think the data requirements are so diverse. We are making strides in certain areas——

Mr. SCHEUER. Are the legitimate needs of these regulatory agencies really intrinsically so diverse? They're trying to control health quality and health cost, aren't they—all of them?

Mr. MILLER. No; there are requirements from EEOC; there are requirements in the personnel area; there are requirements as to physical safety standards. Those would not be in any way dented by a uniform reporting system of data. It would probably not satisfy the data requirements for the medicare program or the

medicaid program. What is needed is someone to take a good commonsense approach and just say, "we don't need duplicate medicare and medicaid audits of the hospital."

Mr. SCHEUER. Supposing Congress directed the administration to have a 1-year long, or 2-year long study of overlapping and duplicative data requirements from the regulatory agencies at the Federal, State, county, and city levels, plus any other levels I have forgotten—and said, "please get your act together."

I quite understand when you talk about building codes requirements, and equal opportunity requirements. Those data needs are somewhat apart and different.

But in medicare and medicaid, and the State and county departments of health, they are looking pretty much at health quality and health cost. It seems to me the preponderance of the data they need could be standarized at the Federal, State, and county and local levels. Maybe even the data you're talking about by EEOC could be standardized. I don't know. But it seems to me that the effort ought to be going on.

Mr. MILLER. I certainly concur, Mr. Chairman. I think that would be most appropriate. It is not now being done.

Mr. SCHEUER. But you would favor that being done?

Mr. MILLER. I certainly would favor that being done.

We're working on getting a uniform billing form. It's been years in coming; a single billing form that could be used to submit billings to medicare/medicaid and some State insurance programs, and we've had tremendous problems with it.

Mr. MILLER. Mr. Chairman, in the interest of time, I will skip over to the conclusion of the written statement, and would like to review that with you, if I might.

I think that broad based involvement of a number of people within Government and from the private sector will be required to achieve the objectives set forth in the report on health technology management at HEW and the technology management strategy which was outlined by Dr. Richmond in February. I know that health care providers will be eager to participate at every level and will take their task very seriously. Medical schools will also need to be involved very heavily if the application and development of technology is to be more effectively shaped for the future.

The role of the office should be advisory and positive incentives should, in my opinion, be given the strongest possible emphasis for achieving the goals of this new public effort.

Lastly, the development of the programs associated with this effort must give great weight to increasing the quality of health and health care services, to preserving the prudent prerogatives of physicians, and strengthening the free enterprise system which has made so many of our American achievements possible.

Mr. SCHEUER. I would agree with almost everything you said but this rhetoric in the last sentence "prudent prerogatives of physicians."

What we're trying to do is sort of give the prudent prerogatives of physicians the salami treatment, aren't we? Aren't we trying to cut down on the prudent prerogatives of physicians, and transfer those prerogatives, to some extent, to hospital administrators and other people who would have more sensitivity to the cost implica-

tions of decisions made by physicians with all of their prudent prerogatives?

Mr. MILLER. Well, I think we have to approach this from the perspective of maintaining the physician/patient relationship. I think we have to approach it from the perspective of recognizing that the physician is in the sole and single position of determining what is best for his patient at that point in time.

Mr. SCHEUER. I beg your pardon. He can't be. And this is what these hearings are all about. He has had that sole unique responsibility, and we have seen health care costs soar into the stratosphere.

Now, what we're saying is, without getting involved in breaching the physician/patient relationship, someone else is going to have to factor some cost concerns into decisionmaking by physicians. Isn't that what we're saying in this hearing?

Mr. MILLER. What we're saying—or what I'm saying, is that the system has, in the past, rewarded inefficiency and not placed the provider at risk and enforced some tough decisions to be made by the hospitals. Yes; I agree with that. And to that extent it will influence the alternatives available to the physician in making his decisions.

We're saying that certain service is not going to be made available, and that would be the decision of the hospital administrator and the community through the HSA.

There will be services that will not be made available.

Mr. SCHEUER. Under certain conditions, for certain particular patients.

Mr. MILLER. Now, my point would be that, while there is some question about how fast it's moving, the PSRO program is the appropriate mechanism to monitor medical practice patterns in this country—and if it needs to be strenghtened, that should be considered.

Mr. SCHEUER. I think it needs to be strengthened.

If you look at the experience of New York State, you would have some very great misgivings about how it has functioned thus far.

Maybe there are some other ways that we can crank cost-saving incentives into the machinery. I'm not sure what they are, but I would hesitate to say that the PSRO mechanism is the only way we're going to do this. It's probably too soon for us to come up with any hard and fast conclusions about how it's worked nationally. It is certainly one way, but I would suspect and hope that there might be other ways that would be equally or more effective.

Well, again, we have run over our time with you, Mr. Miller, and we are very grateful to you for your testimony.

We are going to continue with the third witness, Edwin C. Whitehead, chairman of the board of the Technicon Corp., but now we are going to have a 5-minute break before we hear from Mr. Whitehead.

[Whereupon, at 12:30 p.m., a short recess was had.]

Mr. SCHEUER. The hearing will come to order.

All right, Mr. whitehead.

[The prepared statement of Mr. Edwin C. Whitehead, chairman of the board of Technicon Corp., Tarrytown, N.Y., is as follows:]

Technicon Corporation

OFFICE OF THE CHAIRMAN

STATEMENT

BY

EDWIN C. WHITEHEAD

CHAIRMAN OF THE BOARD

TECHNICON CORPORATION

TARRYTOWN, NEW YORK

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL

SCIENTIFIC PLANNING, ANALYSIS AND COOPERATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

UNITED STATES HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 1978

Tarrytown, New York 10591 / Telephone: 914-631-8000 / Cable address: Techintlab Tarrytown, New York / TWX: 710-567-1220

Mr. Chairman and Members of the Subcommittee:

Thank you for inviting me to appear before your subcommittee to discuss the impact of technology on health care in America.

I am Edwin C. Whitehead, co-founder, Chairman, and Chief Executive Officer of Technicon Corporation, a $250 million, New York Stock Exchange international company with a 40-year history of innovation in medicine.

Among the innovations which Technicon has been responsible for are:

1. The Autotechnicon automated tissue processor to reduce the time for surgical pathology reports from four or five days to 24 hours.

2. The first Fraction Collector which made practical the widespread technique of fractionating proteins into amino acids.

3. The first direct writing Electrocardiagraph.

4. The first portable body respirator, allowing patients to be removed from iron lungs.

5. The first device to perform plasmaphoresis which today is used both therapeutically and to harvest blood fractions.

6. AutoAnalyzers, the first devices to automate chemical blood testing.

7. SMAs - the first devices to allow automatic multiple tests on the same blood sample.

At present we spend some $20 million a year on research and development, roughly 8% of sales, and we get no government support for any research and development. By tha way, we have not had any government help in the past for any of the above developments.

I welcome the opportunity to share with you some of the experience of the Technicon Corporation in the development of medical instrumentation and offer suggestions as to how technology can better meet the need for cost containment.

Until quite recently, tha concern of the Federal government with health care has been almost exclusively to improve its quality and to widen patient access. I refer specifically to such things as the Hill-Burton Act and expansion of coverage through Medicare and Medicaid, as well as federal government initiatives in the development and seeding of new technologies.

Now a serious concern is being shown by government with the high and rising cost of care. Technology can and should play an equally important role in responding to this concern. The industry of which my company is a part is making available methodology that has the potential to greatly reduce the cost of care. Technology in the form of automation has the capacity to reduce the cost of health services by improving productivity just as it reduces the costs of other services. It is paradoxical that the government that is placing heavy emphasis on constraining health cost increases has not only failed to create the proper climate for encouraging the use of cost-lowering

technology but has actually created serious impediments to its adoption.

The current myth prevailing about the medical care industry has it that technology is never used to reduce costs, but only to make possible more complex treatment whose costs are not justified by the resultant benefits. These costs comprise not only increased capital investment but increased operating costs required to use the new technology. This myth, however, differs widely from the facts. I shall present evidence I have gathered in the last 40 years.

Mr. Chairman, in my opinion, there are three kinds of medical technology:

First, that which increases costs but does not contribute to better health. I regret to say that there have been some instances of this type. While the occurrences have not been numerous, we are happy to say that in those cases the health care industry itself has had adequate checks and balances which prevent broad acceptance and use of such counterproductive technologies.

I refer you to three examples, each of which worked well technically, but none which added enough medical benefit to justify the cost involved. In each of these cases, normal market forces have resulted in the out and out withdrawal of the technology from the producing company's product line.

The first of these products is known as a Vector Cardiagraph. Many years ago, cardiologists felt that it was important to learn the spatial relationships of the electrical currents generated by the heart, rather than to simply measure the current generated from the heart to the arms and legs.

Experience quickly proved that the "Vectors" had little medical significance and today there are few if any Vector Cardiagraphs in use. Incidentally, we made the first commercial Vector Cardiagraph.

The second example would be the practice of freezing duodenal ulcers. For a short period of time, patients were put to a great deal of trauma and expense under the pretext of curing ulcers. The medical community quickly rejected this technology.

The third example is a mass spectrometer for measuring the gaseous anesthetic content of the breath of patients on the operating table. Again, medical people have indicated that the cost of this instrument, which works well technically, is not justified. As a result, very few were ever placed in operating rooms and the product has died a natural market death.

A second type of medical technology is that which improves the quality of life but is extraordinarily expensive. I refer you to such things as renal dialysis for kidney disease, open heart surgery, or total hip replacement, all of which either save or improve the quality of life. Certainly nobody seriously opposes their continued development or implementation. But we must recognize that they are a significant contributor to the increase in total health expenditures.

A third type of technology is that which improves the quality of life and reduces the cost of health care to the patient. This is where my corporation's primary emphasis has been. As an example, we provide to the marketplace a line of blood analyzers which possess the capability of automatically performing either single or multiple chemical or hematological analyses.

Mr. Chairman, if I may take a moment, I would like to acquaint you with some facts concerning the cost savings of these products. The first example is based on data collected by the College of American Pathology from several thousand chemistry laboratories nationwide. It provides visible testimony to the cost savings attributable to automated technology.

C.A.P. DATA
LABOR REQUIREMENT OF
VARIOUS CHEMISTRY TECHNOLOGIES
FOR A 20 TEST PANEL

	Manual	Single Channel Automated Instruments	Multi-Channel Automated Instruments
Time (not including set-up)	211 min.	96 min.	8 min.
Cost @ 15¢/min.	$31.65	$14.40	$1.20

The next example comes from a text prepared by Rex B. Conn, M.D., then at Johns Hopkins Hospital. Concentrating on a single common test (Glucose) he adds the cost of reagents and instrument depreciation to provide a total cost.

As can be seen, automation greatly reduces the cost of running this test.

JOHNS HOPKINS HOSPITAL

GLUCOSE COST/TEST

	Manual	Single-Channel Automated Instrument	Multi-Channel Automated Instrument
Labor	$1.20	$0.24	$0.03
Reagents/ Supplies	0.45	0.35	0.12
Instrument Depreciation	0.04	0.06	0.10
Total	$1.69	$0.65	$0.28

The final example is drawn from a text presented by Richard Lent, M.D., of Montefiore Hospital, New York. It provides evidence documenting the overall effects of automation in the laboratory of a large metropolitan hospital. It shows definitively that automation has improved response time and answers large increases in demand, providing both more and higher quality diagnostic information to the physician, while holding the costs per patient cared for, constant.

MONTEFIORE AND ALBERT EINSTEIN LABORATORY
IMPACT OF AUTOMATION

	1965	1975	Change
Inpatients served	13,318	22,740	1.7X
Outpatients served	60,151	234,192	3.9X
Tests performed	214 thousand	2,213 thousand	10.3X
Budget	$562 thousand	$1,126 thousand	2.0X
Budget in constant 1965 $	$562 thousand	624 thousand	1.1X
Cost per test in constant 1965 $	$2.63	$0.29	9.1X less
Results to floor	5 PM	12 Noon	5 hours sooner

In other words, the number of patients cared for increased more than four times and the number of tests performed on these patients increased more than ten-fold, with essentially no increase in the overall laboratory costs in constant dollars, and with a significant improvement in the laboratory's services to the hospital's physicians.

Mr. Chairman, it should be emphasized in addition to cost savings the AutoAnalyzer became an important tool for early detection of disease. It is impossible to calculate the benefits to preventive medicine that innovations such as this have had on our health care system.

The same formula of cost saving and disease detection can be applied to other technology advances. Technicon has introduced hematology, histology and immunoassay systems, all producing similar cost savings with improved advances.

I know others in the private sector are able to provide examples of similar technological advances.

Mr. Chairman, I have cited these advances to emphasize a single point, that is, increased health care costs can not necessarily be attributed to the capital investment in new technology. In fact, often the contrary is true. That is not to say that technology has not been an important factor in the increase in health expenditures. This is because it has given health care much of its capacity to cure. Technology changed the hospital from past house to a place where very seriously ill patients are made well. Inhalation anesthesia and antiseptic surgery came into use after the middle of the nineteenth century. Then for the first time hospitals became able to help many of their sickest patients. Technology provided the basis for this transformation, and none of us would wish to turn back the clock and lose its gains.

The issue confronting us now is to what degree we should support a continuing expansion of total health care. The answer depends not only on the cost of doing this, but also the benefits associated with it. If the answer in general is that further use of our resources for health care should be tightly restrained, then federal research grants in health care should be re-directed to de-emphasize the development of techniques, like renal dialysis, that extend life but at a very high cost. If cost restraint is our primary objective, research emphasis should be shifted to processes that improve the effectiveness and efficiency of care, and that lower its cost. The government's response, in this case, should be to create an environment whereby the private sector may respond with appropriate technologies.

Mr. Chairman, I emphasize that technology is not always cost-increasing. Technology is the factor that emptied our psychiatric and tuberculosis hospitals. There are only one-third as many patients in psychiatric hospitals now as there were in 1955, and almost all TB hospitals have been closed. Antibiotics have reduced the seriousness of infectious diseases and vaccines have almost eliminated the threat of poliomyelitis.

Furthermore, some technology has been designed specifically not to change treatment, but to improve the productivity of health services, producing a better product with fewer employees. Much of the equipment my company has developed without the aid of federal funds goes in this direction.

Our work has also had (as I noted in describing our products earlier) the beneficial side effect of improving the accuracy and completeness with which some of the tasks of a hospital are performed.

One of the newer contributions toward increased health labor productivity offered by Technicon is our medical information system (MIS). This system optimizes the use of high capacity computers and other related devices to record the making of a medical treatment decision and automatically translates this decision simultaneously into orders and convenient records whenever they are needed -- the pharmacy, nursing stations, accounting department and medical records -- all with perfect accuracy. We have placed this system here in the Washington area at National Institutes of Health Clinical Center and dramatically improved efficiency while reducing chances of error.

This example illustrates the labor-saving capacity of medical information systems by doing better what is now being done. But Medical Information Systems have other cost saving and care improving potential. Ours can communicate orders for tests and deliver the results more rapidly than present methods, thus contributing toward reducing length of patient stay. It eliminates the problems of illegibility or transcription errors.

It provides convenient summaries of current treatment orders, reducing the likelihood that conflicting orders will go unnoticed. It provides the opportunity for rapid feedback of results of the use of new drugs or techniques, and this feedback can make a major contribution to technology assessment. It makes possible the inexpensive collection of data covering a combination of services, patient characteristics, and cost. Obviously I see Medical Information Systems which are properly designed and which have a management team concept as being a tremendous asset to the health system.

While most knowledgeable observers agree that the devices I have described increase the productivity of the hospital personnel that use them, many have concluded that cost reductions are nevertheless not realized. As a consequence, a fear to apply promising technology has developed. Planning agencies and the Federal government are among those that exhibit symptoms of this fear. This fear has produced a hesitancy to decide and a tendency to procrastinate while at the same time deploring the decline in productivity gains in the United States. Rather than pressing hospitals to adopt cost-reducing systems, we create barriers to cost saving technology through the reimbursement system and planning agencies. We are allowing self-doubts to control our futures rather than using the ingenuity for which this country has long been noted.

The failure to use new devices to improve cost-effectiveness is not a fault of companies like mine. We have no control over the use to which hospitals apply the saving yielded by productivity improving equipment. One reason for the failure is the greater importance that has been placed on

improvement in care as opposed to cost reduction. As a result, when improved productivity produces a saving, care improvement is often preferred to a cut in price. The system used to reimburse hospitals has tended to fully cover all costs, including those of the improved care. The system offers no reward for cost-cutting and, generally, no penalties for cost increases. In fact, the reimbursement methods actually inhibit cost reduction through substituting capital for labor. Labor costs are fully reimbursed when made, while capital costs are reimbursed slowly, generally on a straight-line depreciation basis, over the life of the equipment. Start-up costs during a period of changeover from one system to another often pose a cash flow problem to the hospital.

There is no Federal aid to hospitals to help them solve these problems in their cost reduction efforts. Also, the failure to develop Federal policy and guidelines on the efficacy of various devices has left the planning system unprepared to decide when productivity-improving investments should be approved. Possibly more important, there is no direction to planning agencies on requirements they could apply as conditions for approvals that would provide assurance of effective use. There is usually no coordination between on one hand, approval of the installation of equipment on the grounds of cost reduction and, on the other hand, enforcement of the cost reduction through the reimbursement system.

Mr. Chairman, while our present problems are many, I reject the hopelessness with which many seem to view the health care system, its costs, and its technology. I believe that we have it within our power to develop further the methods and devices available to us for improving the productivity of the health care system. Private industry and Federal government research each have their share in this activity. We have the intelligence to correct our reimbursement system to provide the incentives needed to induce the realization of the cost reduction potential offered when labor saving devices are installed. We have sufficient commitment to the health planning program to allow us to use it not only to eliminate the excessive barriers to investment in productivity improvement but also to provide positive inducement to do so. I have enough optimism that we will take the proper steps to realize all these potentials.

Thank you.

TESTIMONY OF EDWIN C. WHITEHEAD

Mr. WHITEHEAD. By way of introduction, I am cofounder and chairman, and chief executive officer, chief cook and bottle washer of a company called Technicon Corp., a $250 million, New York Stock Exchange international company with a 40-year history of innovation in medical technology.

Just very briefly, we made the first instruments to process tissues after surgical operations, reducing time for cancer diagnosis from 4 days to 1; the first fraction collector to allow practical separation of proteins into amino acids; the first direct writing electrocardiograph; the first portable body respirator used in place of an iron lung.

We invented the process of plasmaphoresis which is used therapeutically and also to harvest blood fractions—a terrible word.

We made the first devices to automate chemical blood testing and these are now proliferated widely.

And we made the first device which provides a large number of tests on a single sample of blood, a high production kind of blood analysis.

At the present time we spend about $20 million a year on R. & D., about 8 percent of sales, and we get zero Government funds. We have taken no money from the Government.

We see kind of a difference in this business environment that we have been operating in for so long. There seems to be a shift in emphasis from quality of health care as the all important ingredient, to access, and to cost problems. This whole morning has been devoted to cost as the important issue.

There is a current mythology that says technology escalates costs. I think it is true in some cases, but, certainly, very untrue in others.

Mr. SCHEUER. One of the things that we are concerned about is that there doesn't seem to be any incentives built into the system to encourage firms like yours to produce technology for reducing costs.

Mr. WHITEHEAD. You know, we devised the things I mentioned purely to improve the quality of medical care with never a thought to cost.

Now, we were just lucky enough to do this by automating these processes, for we are automating processes in a very, very labor-intensive industry, and, by golly, it is cost-effective.

Actually you do things better by automation in most cases in medicine than you do manually, so we also lucked out on cost.

I do think that you are absolutely right, there must be incentives in the system for manufacturers to produce cost-effective technology.

Mr. SCHEUER. Not only technology which is cost-effective, but technology which has as its sole purpose control of cost. Those are two slightly different things. What we're trying to do is build in some incentives to do both of those. And we certainly do not have any incentive to do the latter.

What incentives we have to do the former seem to be a little obscure to me. It seems to be happening, it seems to be growing like topsy, but not because Government has provided any clear

incentives. Maybe Government should improve these incentives. I don't know, that's what we have to find out.

Mr. WHITEHEAD. I think they should.

Mr. SCHEUER. And I would like you, as you go through your testimony, to give us any views as to how we can best structure these incentives.

Mr. WHITEHEAD. You are saving me a great deal of time, I don't have to make the case, you are making it for me.

Mr. SCHEUER. No; please don't say that.

Mr. WHITEHEAD. Well, I would like to make one point. I feel very—well, I guess paranoid, because so many people are equating escalating costs with increased testing.

Mr. SCHEUER. With increased testing?

Mr. WHITEHEAD. Defensive, medicine. "Let's do more blood tests, and so on".

Mr. SCHEUER. Would you doubt that exists to a certain extent?

Mr. WHITEHEAD. I have strong doubts that that exists as a simplistic statement. I have no doubt that the cost of testing has enlarged the health bill.

Mr. SCHEUER. Would you have doubt that some doctors at times prescribe tests that they know in their hearts are not particularly appropriate to this patient and are not really going to give them any information that's helpful, but that they had better do it because at some point in time some lawyer may be asking them why they didn't think of this particular test?

So you have any doubt that happens?

Mr. WHITEHEAD. I have no doubt that happens., I do not believe it is a major factor in escalating costs.

Now, just to support that, a fellow at Montefiore Hospital, Richard Lent, a pathologist, collected some numbers as to what was happening in his hospital in New York. From 1965 to 1975 the number of tests they did increased tenfold; the number of patients increased fourfold. Yet the total cost in 1965, dollars remained constant for the entire laboratory budget.

Mr. SCHEUER. So they did 2½ times——

Mr. WHITEHEAD. They did 11 times the number of tests on 4 times the number of patients.

Mr. SCHEUER. They had about 10 times the number of tests and 4 times the number of patients, so they had 2½ times the number of tests per patient, at exactly the same cost in real dollars?

Mr. WHITEHEAD. No, because they had four times as many patients, so it's much more than that.

Mr. SCHEUER. I see what you mean.

Mr. WHITEHEAD. Four times the number of patients; 11 times the number of tests at the same cost without increasing the cost.

Mr. SCHEUER. Two and a half times as many tests per patient and four times as many patients.

Mr. WHITEHEAD. Yes, sir.

It's kind of staggering.

Mr. SCHEUER. That's remarkable.

Mr. WHITEHEAD. But I don't want you to think that the bill to the Blue Cross or the Government was constant, I don't think it was.

And there is another very interesting phenomenon that happens, and this is why I would like to differentiate between testing and sampling. I think there is a large difference.

It cost about $3 to stick a needle in a patient's vein to get a blood sample. And we provide an instrument that does 20 tests on that blood sample at an incremental cost of 43 cents to the hospital.

Mr. SCHEUER. One charge of 43 cents for 20 tests?

Mr. WHITEHEAD. Yes, sir.

Now, I don't think that is really escalating cost. I really don't. I think those $3 escalate cost. Every time a patient is stuck, I think it's cheaper to do everything on a patient that you possibly can once you have spent the $3 to stick him.

Mr. SCHEUER. The study you cited in New York is one study in the aggregate; however, the total bill is going up at the rate of 15 to 20 percent a year in the national aggregate for laboratory testing.

Mr. WHITEHEAD. Yes.

Dr. Wells. When you look at this in the total price tag aggregate in the range of $15 to $16 billion a year, I still think you have to think in terms of cost-effectiveness. And maybe that initial $3, the needle stick, is the place to look at it, but the point is there's probably a lot more testing being done and should be done on the basis that, if it's almost free, go ahead and do it.

In a single instance it is a minor element; in the aggregate, it becomes a very expensive item when you multiply it by millions of people.

I think one of the things we're trying to get at here is whether or not in this case there are other forces at work leading to the wider use of unit tests that your technology has made very, very inexpensive, yet in the aggregate becomes very expensive because more people do it.

Mr. WHITEHEAD. I don't know. There's some sort of logic that escapes me there: because you could do 20 tests for 43 cents you stick people more often. I don't really understand the logic, but maybe it is. I'm not being facetious, I think it's beyond me, frankly. I just don't understand it.

I know the testing has increased; I know it's more available; I know it's less expensive. I also suspect it has provided some useful information to somebody about something, but that's hard to prove.

Mr. SCHEUER. You know it's less expensive——

Mr. WHITEHEAD. Considerably less expensive in terms of cost.

Mr. SCHEUER. Per test, but in the aggregate the bill is going up alarmingly.

Mr. WHITEHEAD. Right—which is not a simple kind of thing.

Mr. SCHEUER. Maybe one of the reasons it is going up alarmingly is because not enough of these tests are performed the way you perform your tests.

Mr. WHITEHEAD. Yes.

Mr. SCHEUER. We had a bill on laboratory testing, and I put in an amendment that would enable New York City and other cities to put out their testing by auction—taking bids for each of the different kind of testing, and we even broke it down by counties, so the small companies could get into the act.

We had great opposition from doctors and laboratories, and from the whole medical profession. They claimed that putting out these tests by bid and letting companies like yours get into the act with the 20 tests all automated would destroy the patient/laboratory connection—the patient's choice.

And they felt strongly that when a patient came to a doctor, that patient would have the right to determine which laboratory did the analysis of the blood test, and the patient's choice would be breached if we allowed the bid process. So institutionally we have not made it possible to reap the cost advantages of more efficient methods.

Mr. WHITEHEAD. It might interest you to know that in some States—I think there are still one or two—single tests were reimbursed at $5 apiece, and 12 tests were reimbursed at $6.

Mr. SCHEUER. Could you give us or provide us with that information?

Mr. WHITEHEAD. I could get it for you, certainly.

Mr. SCHEUER. Please do that. We will hold the record open for 10 days or 2 weeks.

Mr. WHITEHEAD. Fine. I will get it for you this afternoon. (See appendix p. 295.)

Mr. SCHEUER. Would you be in favor of a mandate for cities and States where the aggregate volume of laboratory testing for medicare and medicaid gets beyond a certain figure, the cities and States must put that testing out to bid, in order to achieve the kind of ecomomies that you have described?

Mr. WHITEHEAD. That's a tough question. I really haven't considered it. I would like to think about it. I just don't know what the effect would be.

May I write to you about that?

Mr. SCHEUER. By all means.

Mr. WHITEHEAD. I would like to because I really haven't considered it.

Well, I think I should consider the point about economies of scale and so on.

Mr. SCHEUER. What is your point about economies of scale?

Mr. WHITEHEAD. We sell a machine for $225,000. It has a 10-year life. If you do 100 samples a day, probably the cost per test—I haven't figured it out, but it's on the order of 20 cents/30 cents.

If you do 300 samples a day it's one-third. If you do a thousand samples a day—which the machine is capable of—then it's very much less. So the economies of scale are really tremendous. It encourages you to use automation in every sense in the laboratory.

The small laboratory cannot process information by computer—billings and all those myriad things the laboratory does—they just cannot do that in an automated way because they can't afford the capital investment.

Mr. SCHEUER. Well, wouldn't you like to have the chance to compete in this business with the cities and States all around the country?

Mr. WHITEHEAD. We're not in the laboratory testing business. We're just in the business of making the machines that do it; but if I were, I think I might; yes.

Mr. SCHEUER. I would think so, too. That's why I think the bid process makes a lot of sense.

Mr. WHITEHEAD. You would have to have very adequate quality control mechanisms to prevent laboratories from underbidding and not doing quality work; but, I think that's possible.

Mr. SCHEUER. Isn't it easier with large-scale operations that are well automated than the little neighborhood testing laboratories that perhaps depend on more labor-intensive processes where you get all the vagaries of the human condition cranked into the process?

Mr. WHITEHEAD. Yes.

I would like to refer for just a minute, if I could, to your idea of uniform reporting which the previous witness was testifying about. I think that it is quite important. And as you so correctly point out, the amount of paperwork and its cost in a hospital is outrageous.

We, among our other activities, make a computerized medical information system, a hospital system. As an example, at one rather small community hospital, 450 beds, we eliminated 3 million paper forms in a year, and, naturally, the people to do it.

The Department of HEW studied the system, particularly its impact on nurses, and they discovered that nursing time was roughly 40 percent spent in clerical work, just form filling out, you know, keeping the records and so on. A system of this sort reduces it to 10 percent, which is very attractive.

If there were uniform reporting systems of the kind you're talking about it would be almost a trivial matter for an automated information system to provide the records and, I think, reduce cost substantially. The development of a million different programs to do a million different things to satisfy a million different agencies is very expensive, just in the soft-wear department; but if there were some uniformity, we would embrace it enthusiastically, and I think the result would be substantial savings, really substantial.

We have a medical information system that is used in about 11 hospitals now. I think the hospitals that have it are quite proud and pleased with it.

Mr. SCHEUER. Are there any of then in New York, as a matter of interest?

Mr. WHITEHEAD. There's one coming, but not yet.

Mr. SCHEUER. Could I ask which one?

Mr. WHITEHEAD. I would rather not——

Mr. SCHEUER. Could you get us a list of the hospitals that are operating it?

Mr. WHITEHEAD. Yes; I could do that.

Mr. SCHEUER. You could submit it to us and maybe we would like to ask them how it works.

Mr. WHITEHEAD. OK, I will.

My point was that we are selling a system which I think the studies have shown has been successful in reducing errors and making more efficient patient care and making the hospital a better environment to work in. So one can properly ask the question—which is probably my duty as chairman of my company—"why are not these systems proliferating"?

I think the answer is simple, because there is no incentive for anybody to acquire the system.

To acquire a system of this sort, which is comprehensive in every aspect of patient care, and operating the hospital, to install such a system means the education of about 3 employees per bed; in a 500-bed hospital, 1,500 people.

When you are done with that, you have got to approach a group of physicians, who really are essentially enterpreneurs and have no particular allegiance to the hospitals. You have to approach their work in a different manner because they have a built-in antagonism, I think, to computer systems.

This is almost revolutionary in the average hospital, and the administrator says, "gee, it's great, I'll be a better hospital, everything will be wonderful," and what will happen is the department heads will think "my reimbursement will go down and my budget will be less, I'll have less power, less influence and less flexibility. I am not terribly enthusiastic to go through such a revolution to have such a result." Which is perhaps the reason that these systems have not proliferated as widely as we originally expected.

Mr. SCHEUER. What you are suggesting then is that we need some kind of profit sharing.

Mr. WHITEHEAD. Yes, sir.

Mr. SCHEUER. Why don't you elaborate on that and tell us how you would structure incentives?

Mr. WHITEHEAD. I think there are two incentives essential in the system.

First of all, hospitals must have some form of performance criteria that includes not only quality—which there is lots of now, but also productivity. And I think we should reward the efficient provider, and, at the same time, perhaps, penalize the less efficient provider.

I really think that's the ony way——

Mr. SCHEUER. Now, how could we do that? Give us some specifics.

Mr. WHITEHEAD. I will start out by saying that it is a very difficult task.

You have to start out with a peer system, and we have to structure the categories of hospitals in a very meaningful way.

In other words, a Catholic hopsital in St. Louis would be entitled to have 200 beds compared to a Baptist hospital in Omaha of 200 beds, but their patients make a little difference, so you compare them in OB and GYN, but maybe in internal medicine and find they are different.

You have to find peers and standards and review the differences. It's an enormous task. I admit that and understand that. But, once it is done, then you could set up standards of performance and measure the hospitals against those standards, and allow the hospital that is a proficient provider to retain some of the benefits he has been able to achieve.

Right now he doesn't retain anything.

Mr. SCHEUER. Therefore, he doesn't have any incentives.

Mr. WHITEHEAD. Exactly; zero incentives.

I think it is an enormously difficult task to do it that way. Maybe there is a better way to do it than the peer review and comparison system, but I think even the latter is worth it. I think

the game is worth it from the millions and billions of dollars that are going out.

Mr. SCHEUER. It's now up to about a fifth of a trillion dollars—that's with a "TR".

Mr. WHITEHEAD. Right.

I think there is another problem. I happen to feel very strongly, like most, that the only way to have a meaningful reduction in cost in hospitals is by capital investment. Hospitals are 70 percent labor, or it varies between 55 and 70. If you really want to reduce cost, you have got to do something about the labor figure.

Most hospitals do not have the capital and means for raising the capital to make the front-end investment. So, it is very tough for it to effect productivity.

If the Government could figure out some way to make money available to these hospitals, to be reimbursed in the in the future out of future savings, I think that would help enormously in containing the escalating cost.

There is another unfairness that goes on in the reimbursement system I believe. Labor is fully reimbursable under the system. Capital is reimbursable in a straight-line depreciation over a very long period of time. So it's far more attractive and very much easier for hospital to make investments in labor, and that has the effect of escalating costs.

Mr. SCHEUER. Whereas additional capital could save far more than its cost through the labor-savings that it could produce.

Mr. WHITEHEAD. I think there's an incentive to do this, because if they don't, the hospital could not repay. Therefore, to the the front-end money, hospitals would see to it that it pays off.

Mr. SCHEUER. In other words, you're going to have to provide hospitals with that funding, front-end money?

Mr. WHITEHEAD. I think we have to provide hospitals with the front-end money for the very expensive technology. There is some technology, of course, that is easily acquired out of operating funds, but I think if we could encourage the hospitals to make capital investments to increase productivity this would be very powerful incentive, and they would take it.

I don't think I have anything else to say.

Mr. SCHEUER. I agree with you wholeheartedly. You are right on target with our thinking. As to how we do these things, that's the big question. But in principle, you are right on target with our thinking. Dr. Wells, do you have any questions?

Dr. WELLS. No, Mr. Chairman.

Mr. SCHEUER. Dr. Murray?

Dr. MURRAY. No, sir.

Mr. SCHEUER. Mr. Whitehead, thank you very, very much. And we will look forward to receiving the information that you indicated you would give us, both as the list of hospitals that are using you system and as to some of your other thinking.

Mr. WHITEHEAD. Yes, sir.

Mr. SCHEUER. And we probably will be following up with several other questions.

Mr. WHITEHEAD. Please do.

Mr. SCHEUER. Thank you very, very much.

Mr. WHITEHEAD. Thank you.

Mr. SCHEUER. We will now hear our last witness for today, Mr. Clyde J. Behney, M.B.A., Senior Analyst, Office of Technology Assessment, and the OTA Study Director for a study entitled "Assessing the Efficacy and Safety of Medical Technologies."

[The prepared statement of Clyde J. Behney, M.B.A., Senior Analyst, Office of Technology Assessment follows:]

STATEMENT OF

CLYDE J. BEHNEY, SENIOR ANALYST

OFFICE OF TECHNOLOGY ASSESSMENT

CONGRESS OF THE UNITED STATES

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC

PLANNING, ANALYSIS, AND COOPERATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

U. S. HOUSE OF REPRESENTATIVES

SEPTEMBER 26, 1978

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MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to appear before you to discuss recent work of the Office of Technology Assessment. I am especially pleased because these hearings address medical technologies and their effects or impacts as a generic public policy issue. This type of focus, by either legislative or executive branch policymakers, was virtually unheard of until recent years.

One of the prime expressions of the overall "technology" problem is a lack of knowledge about what the direct medical and economic effects or the indirect, often long term, effects of technologies on society are or might be. The result of that problem is an inability to fully manage the effects of technologies to our best advantage. Whether we talk about a particular drug, or electronic fetal monitoring, or a clinical laboratory test series, or coronary bypass surgery -- we are addressing technologies. And as technologies these medical tools possess certain common characteristics. For example: development patterns, or, incentives for their use or disuse. Understanding these characteristics is very important to our ability to anticipate and plan for the impacts of using these and other technologies.

The essential first step toward ameliorating this situation seems to be taking place at the present time. The policy debate is more and more focused on "medical technology" (or on "technology" in general) rather than taking the form of narrow reactions to specific expressions of what are generic, or root, problems. These hearings are one example of this essential first step. So, too, was the establishment of the Office of Technology Assessment and of a Health Program within that office.

The Office of Technology Assessment was established in 1972. It is, as you know, an advisory arm of the Congress. Its basic function is to help legislators anticipate and plan for the long-term consequences of technological applications, and to examine the ways, expected and unexpected, in which technology affects peoples' lives. The Health Program was formed in 1975 and has issued reports on a number of health-related technological applications. Dr. David Banta, the Health Program Manager, will be discussing these reports and OTA in general later in these hearings so I will confine my remarks to our report on "Assessing the Efficacy and Safety of Medical Technologies."

Before going into some of the specifics of that report, I should mention how the study was conducted.

The study was requested by the Senate Committee on Human Resources. It was conducted by staff of the OTA Health Program with the expert assistance of an outside advisory panel. The chairman of that panel, Dr. Lester Breslow -- Dean of the School of Public Health of UCLA -- will be appearing before you tomorrow. The panel was chosen to represent various sources of expertise and various parties-at-interest, such as practicing physicians, consumers, and the health insurance industry.* The panel helped to plan the study, as did several Congressional committees, and reviewed all drafts of the report. The final content of the report, however, is the responsibility of OTA.

Efficacy and safety may be viewed as the direct medical benefits and risks of a technology. They are extremely complex concepts. However, they can be evaluated, or "measured." Evaluation of efficacy and safety centers around isolating the magnitudes and probabilities of occurrence of the benefits and

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* A list of the Advisory Panel members is attached.

the risks associated with using a particular medical technology. The benefits and risks depend on: (1) the medical condition for which the technology is applied; (2) the population or characteristics of the individuals for whom it is used; and (3) the conditions under which it is used. For efficacy, these conditions of use are considered to be "ideal," or, as a surrogate, well controlled research settings. OTA differentiates efficacy from effectiveness, which is the benefit measured under average or normal practice conditions -- that is, when the technology is actually used in medical practice.

In this report, OTA concludes that the assessment of efficacy and safety is an extremely important starting point in the evaluation of the overall social usefulness of medical technologies. They are prime criteria for judging the technical effects of the technologies in question. Any person or organization using or directly affecting the use of medical technologies is a user of efficacy and safety information. Some of these parties-at-interest are:

patients
physicians
other health care professionals
biomedical researchers
health services researchers
government regulatory programs
government and private reimbursement programs
health planning agencies
quality assurance programs
other Federal and State health agencies
medical schools and public health schools

Obviously, whether the use of a technology yields benefits commensurate with the associated risks is of critical importance to both the quality and the cost of medical care. All the groups and individuals listed above need information on the appropriate uses of technologies.

One of the reasons we were asked to examine this topic was the increasing concern about whether such information was lacking for many medical technologies. That is, are medical technologies evaluated adequately before they come into widespread use. Some obviously have; others obviously haven't. Nobody can know the exact proportion of technologies which have, or have not, undergone adequate evaluation for effiacy and safety before diffusion into medical practice. Dr. Kerr White has estimated that perhaps only 20% of medical and surgical procedures have been adequately assessed. The efficacy of medical devices has only recently been brought under the jurisdiction of the Food and Drug Administration.

However, it was the consensus of our advisory panel, and of the experts from Fedeal agencies with whom OTA consulted, and of many other health policy experts, that in general there is a significant number of such inadequately assessed technologies in use. There are many examples of medical technologies that came into use and only later were found to be inefficacious or unsafe. Such technologies as gastric freezing, lobotomy, colectomy for epilepsy, lumbo-dorsal sympathectomy, and uterine suspension are examples. And there are technologies in use today whose efficacy and safety have been seriously questioned: for example, oral drug treatment for diabetes, respiratory therapy, oral decongestants, thermography, mammography, radical mastectomy, electronic fetal monitoring, tonsillectomy, coronary care units, and coronary bypass surgery.

Given then the probability that many medical technologies enter medical practice with inadequate evaluation of their efficacy or safety, OTA then concentrated on discovering reasons for this premature diffusion and inappropriate use. We focused on the existing mechanisms for generating information on the efficacy and safety of medical technologies.

OTA concluded that any system to generate information on efficacy and safety should have, in greatly simplified terms, four basic elements:

IDENTIFICATION, which consists of monitoring technologies, selecting those in need of study, and deciding to study;

TESTING, which consists of conducting the appropriate analyses or trials;

SYNTHESIS, which consists of collecting and interpreting existing information and new information resulting from the testing step and usually includes making recommendations or judgments on efficacy and safety; and

DISSEMINATION, which consists of providing the synthesized information and any other relevant information to the appropriate parties who use medical technologies or make decisions concerning such use.

We examined the current Federal and private systems and programs for generating and disseminating efficacy and safety information in an attempt to see whether these four functions were being fulfilled and were adequately coordinated.

Our findings indicate that there are serious shortcomings in how these four functions are being carried out. Our first finding is that there is no formal or well-coordinated system for assessing efficacy and safety either before or after a technology is diffused. The DHEW Technology Management Strategy study and its

newly created Office of Health Technology are an attempt to fill that gap. The only technologies being systematically examined before diffusion are new drugs. However, the standard used to assess the efficacy of drugs is whether the drug will do what the manufacturer claims it will do. Thus, even new drugs do not always receive an adequate evaluation of their efficacy. This point is particularly critical in that practicing physicians may use a drug for medical conditions for which it was not evaluated by the FDA.

The identification phase is particularly important because it is there that decisions are made as to what technologies should be studied. It would be an impossible task to evaluate all aspects of the efficacy and safety of every medical technology. The task would be fiscally and technically overwhelming. OTA identified a lack of a relatively complete inventory of technologies. Further, no agency presently has the capability to anticipate new technologies that should be assessed. Such identification that does take place is often based on such criteria as investigator curiousity, research needs, and so on, and is normally done by the agency doing the testing. Relatively little attention is paid to the needs of, for example, regulatory agencies. In sum, there is no formal process for selecting which technologies, new or existing, are to be studied. Indeed, there is not even a set of priorities for such selection.

Testing of efficacy and safety may be accomplished through preclinical techniques, analysis of clinical experience, epidemiological techniques, controlled clinical trials, and development of a formal consensus. These techniques may be used singly or, far more commonly, in some combination. Each is important; each has its particular uses, its strengths, and its weaknesses. The controlled clinical trial has emerged in the past two decades as perhaps the most powerful tool for scientifically-based evaluation of efficacy and safety. Questions have

been raised about whether the level of funding for controlled trials is adequate. OTA concluded that there is no "correct" level of funding for clinical trials but found that the current effort represents a very small portion of the Federal funds expended on biomedical and health services research. The shortcomings in the testing phase are intimately tied to the identification phase. Some of these are: existing technologies are studied much less frequently than are new ones. Preventive technologies are studied much less frequently than are therapeutic ones. A large percentage of the controlled trials funded by the Federal government are for cancer drugs; a small percentage are medical and surgical procedures.

Federal government activities in the area of synthesis are expanding but still represent a modest level of effort. The NIH in particular has increased its synthesis activities. The result of these "consensus development" conferences cannot yet be predicted, but there is great potential for providing widely accepted and useful information. The synthesis phase depends heavily on the products of the first two phases. The shortcomings in those systems have minimized the amount of well-validated data that is available for synthesizing. That point highlights the interdependence of the four phases. Coordination and management of the assessment process is critical to its ability to provide us with needed information.

Federal agencies have not assigned a high priority to dissemination of information on efficacy and safety. The private sector is expanding its efforts in this area. Overall, however, practicing physicians and others in need of information do not receive as much well-validated, relevant data as they need to make clinical or health policy decisions.

Based on our finding of serious shortcomings in Federal systems used to develop and disseminate information on efficacy and safety, and based on the finding that the status of efficacy and safety information is inadequate to assure appropriate use of technologies, OTA has concluded that improvement is needed. Although OTA does not make recommendations in its reports, the report does present alternatives for Congressional consideration.

The first set of alternatives deals with the extent and type of change in the Federal role that Congress may feel is necessary. Improvements in the assessment of efficacy and safety could be left to the private sector, perhaps with Federal stimulation or oversight. Or, the Federal government could expand its activities, either legislatively or administratively. Expansion could take on many forms -- for example, funds for clinical trials could be increased, or a new office or agency could manage or coordinate the whole process. Also, some combination of Federal and private activities could be pursued.

The remaining alternatives in the report address the four functions identified by OTA as being necessary to the development and dissemination of information. For each of the four, possible organizational sites are listed, and possible advantages and disadvantages of each are presented.

I would like to submit for the record excerpts from the report discussing the policy alternatives. I have attached those excerpts to this statement. I would, however, like to mention here the sample attributes that OTA feels would be critical for any agency or office given responsibility for one or more of the functions:

An explicit mission statement, to which it is held accountable;

Statutory or regulatory authorities commensurate with its mission;

Adequate funding for the assigned mission;

A competent, multidisciplinary staff, with expertise in technology development and evaluation;

Credibility and working relationships with the health profession, scientists, industry, third party payers, and government.

That, very briefly, is what our study "Assessing the Efficacy and Safety of Medical Technologies" was all about. I should point out that much of what has been said about the process of assessing efficacy and safety also applies to evaluating other aspects of medical technologies, for example, cost-effectiveness or potential social impacts. The essential steps in a system to generate those types of knowledges would be much the same.

Starting about twenty years ago, people like Bradford Hill and Archie Cochrane began a serious call for more cooperation between clinicians and statisticians in order to improve the information base we use to guide the utilization of medical technologies. That cooperation has been significantly, though not perfectly, realized. Perhaps the next call should be for increased and better planned cooperation among clinicians, statisticians, and public and private policymakers. The decisions made by these groups have become crucial to how technologies are used and to what information is developed. Any effort to improve the use of medical technologies and to thereby control their effects (such as on costs of care) should take this interdependence into account.

Thank you. I will be pleased to answer any questions.

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POLICY ALTERNATIVES

This chapter outlines a number of policy alternatives intended to correct some of the shortcomings in the assessment process presented in earlier chapters. Many of these options do not require new legislation because sufficient authority already has been written into law. In certain cases, desired actions could be stimulated by congressional oversight. Alternatives are presented for each of the four phases of the assessment process: identification, testing, synthesis, and dissemination. Although not previously discussed, several policy alternatives which attempt to translate efficacy and safety information into improved management of the utilization of technologies also are presented. Many of the alternatives and all of the steps of the process are both relevant and applicable to other types of assessments of medical technologies. Cost-effectiveness assessments, for example, could follow the four-step process. In that context, the advantages and disadvantages presented in this chapter would have to be modified to reflect the expanded functions.

The first question to be addressed is to what extent, if any, should the Federal Government either change or expand its activities in the process of assessing efficacy and safety. As described in chapter 5, existing Federal and private mechanisms execute important parts of the task of assessing the efficacy and safety of medical technologies. The Food and Drug Administration (FDA) has the statutory responsibility for assuring safety and efficacy of drugs and devices. Other Federal agencies, such as the National Institutes of Health (NIH), fund clinical trials that produce information on safety and efficacy. The private sector supports a large number of clinical trials, some mandated by FDA legislation. If Federal action were desirable, the four functions described above could be assigned to one agency or divided among several agencies in the Federal Government. They could be developed in one or more existing agencies, or an entirely new agency could be developed. Alternatively, the private sector could be encouraged or provided incentives to expand its activities in these areas. Or, some combination of Federal and private strategies could be pursued. The first question is whether the Federal Government should or should not act; that question must be decided by Congress.

SECTION ONE: CONGRESSIONAL ALTERNATIVES

Alternative A-1: Any change or expansion in the development of information on the safety and efficacy of medical technologies could be left to the private sector. This alternative does not imply that there are no problems in existing private sector activities. This alternative would give Government a twofold role: to stimulate the private sector and to monitor its activities.

Alternative A-2: The Federal Government could expand activities relating to the development of information on efficacy and safety of medical technologies. A series of possibilities is presented later in this chapter which could be followed if this alternative

were desirable. In this alternative, legislation could mandate the performance of certain activities.

Alternative A-3: Some combination of alternatives A-1 and A-2 could be pursued.

Any agency or agencies involved in assessing efficacy and safety could complete this task better if certain criteria were met. As examples, such an agency or agencies might need:

- An explicit mission concerning efficacy and safety assessment. The agency must accept this role and be held accountable for its performance.
- Statutory or regulatory authority to accomplish its mission. For example, it should be able to gain access to information it needs, including access to FDA materials considered to be proprietary.
- Adequate funding for the assigned mission. This might require an existing agency to reorder its spending priorities. In addition, new funding would probably be necessary.
- A competent, multidisciplinary staff with expertise in technology development and technology evaluation. Statisticians, physicians, epidemiologists, sociologists, economists, and others would be essential.
- Credibility with the health professions, scientists, industry, and third-party payers, It would be desirable if the agency already had relationships with these groups. Relationships with practicing physicians are important, particularly because information dissemination to that group would be an important task. Working relationships with other Government agencies involved in technology development and use would also be necessary.

The following sections discuss a series of alternatives to current policy in each of the four areas mentioned earlier. The functions could be addressed in many ways. The alternatives given are not exhaustive, but rather illustrative. Nor are they mutually exclusive. Furthermore, any agency could use a variety of programmatic mechanisms for meeting its objective: grants, contracts, intramural research, and mandating or requesting assessment from those who are able to provide a service. Any or all of these mechanisms could be used by any one agency. The alternatives that follow do not discuss or compare these approaches. (Table 9 summarizes the possible responsible organizations for conducting the four basic functions in efficacy and safety assessment.)

SECTION TWO: IDENTIFYING TECHNOLOGIES THAT NEED ASSESSMENT

A system for identifying technologies that need assessment could be developed in a number of agencies at various levels.

Alternative B-1: A special commission could be established to identify technologies needing assessment. This task will be a lengthy one requiring a special commitment establishing a special commission for that purpose would have some advantages. It could include prestigious physicians as well as experts from other disciplines and lay representatives. Its deliberations could be open to public scrutiny. The major disadvantage in choosing this alternative is that such a commission would be far removed from sources of

Table 9.—Possible Sites for Carrying Out Four Key Tasks in Efficacy and Safety Assessment

Identifying technologies that need assessment	
B-1.	A new commission
B-2.	Institute of Medicine
B-3.	National Institutes of Health
B-4.	Agencies involved in technology development
B-5.	Food and Drug Administration
B-6.	A new Federal office or agency, or the Office of Health Technology
Requiring, stimulating, conducting, or funding studies	
C-1.	National Institutes of Health
C-2.	Other Federal agencies
C-3.	Food and Drug Administration
C-4.	A new Federal office or agency, or the Office of Health Technology
Synthesizing information	
D-1.	A new commission
D-2.	Institute of Medicine
D-3.	National Institutes of Health
D-4.	Agencies involved in technology development
D-5.	Food and Drug Administration
D-6.	Office of Health Practice Assessment
D-7.	A new Federal office or agency, or the Office of Health Techology
Disseminating information	
E-1.	National Institutes of Health
E-2.	Other Federal agencies
E-3.	A new Federal agency, or the Office of Health Technology
E-4.	A new office in HEW

new technologies, including those that might prove to be problematic. Furthermore, new staff and multiple subcommittees would be necessary.

Alternative B-2: The task could be assigned to the Institute of Medicine of the National Academy of Sciences. This is a desirable option because it chooses an extant, prestigious organization for the task. (The National Academy of Sciences previously carried out the task of evaluating evidence of the safety and efficacy of drugs on the market at the time of the passage of the 1962 Food and Drug Amendments.) The institute would probably have good sources of information about development of procedures in academic medical centers. As a quasi-governmental body, the institute could bridge the gap between Government and private sector medicine. The disadvantages of using the institute are the relatively small number of practitioners in its membership and the uncertainty as to whether it would perform such a task.

Alternative B-3: The task could be assigned to NIH. This arrangement is advantageous because NIH administers most of the Federal biomedical research support and a large percentage of the national expenditure. Staff at NIH could be expected to be cognizant of developments even in areas in which NIH has not committed funds. However, NIH has exhibited a stronger interest in developing medical technologies than in assessing them. To some extent, this potential problem could be ameliorated by placing

the function high in the administration of NIH, possibly in a new division or bureau. Such placement might avoid the parochial concerns of the various disease-oriented institutes. Nonetheless, if NIH were assigned this function, careful oversight by the higher echelons of the Department of Health, Education, and Welfare (HEW) and Congress would be essential to assure the effective completion of the task. Another potential problem in choosing this alternative is that the accomplishment of the basic mission of NIH could be hampered by such a new function.

Alternative B-4: Each agency (for example, the National Center for Health Services Research) developing medical technologies could be asked to develop a list of its technologies that would need evaluation. This option would avoid the creation of another bureaucracy. It would also make an important function even more diffuse than it already is, and would lead to a great deal of overlap. In addition, it might leave many extant and new procedures unassessed. There are also potential, informal conflicts of interest associated with this alternative.

Alternative B-5: FDA could be assigned the task. FDA has experience in evaluating new technologies, and many of the same principles used in evaluations of drugs and devices could be applied to the area of procedures, with or without a regulatory program specifically concerned with procedures. The major disadvantage of using FDA is that it has had much more experience in working with private firms than in completing the type of function described here. Furthermore, FDA lacks technical resources and has image problems in the practicing community.

Alternative B-6: A new agency or office could be developed, possibly within HEW, which would be assigned the responsibility for efficacy and safety assessments. Its mission could include any combination of identifying technologies to be assessed, conducting and funding the studies, evaluating and synthesizing the information, and disseminating that information. The advantage in choosing this option is that no existing agency is deeply committed to assessing the efficacy and safety of medical and surgical procedures. Alternatively, it is difficult to establish a new agency, to assign it a mission, to document its need for a new budget, and to recruit expert staff. Furthermore, it may not be desirable to develop a new bureaucracy of this size which would handle all four functions when existent agencies and programs could do some, or most, of the job.

HEW has established an Office of Health Technology which would probably have the identification function within its mandate. The future structure and functions of that Office are unclear, however. If the Office of Health Technology begins functioning, it could engage in any or all of the activities specified in this report. Similarly, there are bills in Congress which would establish Federal agencies or offices that could be assigned many of the assessment functions, including identification.

SECTION THREE: REQUIRING, STIMULATING, CONDUCTING, OR FUNDING STUDIES

Expanded support for efficacy and safety testing could be developed in a variety of ways:

Alternative C-1: NIH could assume a larger role in testing both new and existing technologies for efficacy and safety. This option has the advantage of assigning the function to an agency that is already familiar with the field and, therefore, best equipped to

identify developing technologies. This alternative is disadvantageous because not only has NIH been reluctant to assume such an expanded role without new funding, but also NIH has resisted becoming deeply involved in existing medical practice. One method of realizing this option might be to develop a new program or bureau at NIH. The option would be most effective if new money were appropriated to NIH.

Alternative C-2: Other Federal agencies could be asked to expand their roles. The Veterans Administration (VA) is an obvious choice because it offers an excellent field for testing efficacy and safety due to its activities within a medical system that is quite practice oriented. However, VA's funds for medical research are limited, and most of its population is comprised of adult males. Furthermore, VA lacks connections both to HEW and the general community of practitioners. Nonetheless, VA and other agencies could make important contributions.

Alternative C-3: FDA could be given a larger role. However, FDA's experience is in administering a regulatory program, and it is not clear that procedures could be studied in a way analogous to regulation of drugs and devices. In addition, FDA has limited contacts with clinical researchers who could conduct the requisite studies.

Alternative C-4: A new agency could be developed in HEW to fund and conduct efficacy and safety testing. This option incorporates recognition of the fact that the function requires new staff and funds and an organizational focus, and that it would be difficult to change dramatically the mission of an extant agency. The major problem associated with this alternative is that of developing an entirely new agency. This problem could be partially overcome by assigning experts from existing agencies to the new agency. If a new agency were developed, it also might be an appropriate site for identifying technologies that need assessment. An agency with a vested interest in evaluating efficacy and safety could be expected to be active in identifying candidates for evaluation.

Studies would not have to be federally funded. Under FDA statutes, for example, the greatest expense of testing is borne by the manufacturers. If proof of the efficacy and safety of procedures were required by private and public third-party payers, private funding could support more of this testing. Third-party payers also could fund studies directly; National Blue Cross, for examle, has funded a study by the Institute of Medicine on the efficacy of the computed tomography scanner. If successful, this model probably could be used more often. Much of the current testing of medical and surgical procedures is already supported by private funds, including service funds.

SECTION FOUR: SYNTHESIZING INFORMATION

Merely executing numerous research studies will not solve the problems of assessing the efficacy and safety of medical technologies. More data certainly will be helpful, but gaps in knowledge still will remain. Furthermore, value judgments are an integral part of making decisions of efficacy and safety. For example, the net benefit of a technology includes both efficacy and safety; yet, these two parts of the concept cannot be measured in fully comparable terms (see chapter 4). Value-based decisions must still be made regarding whether the positive benefit (efficacy) justifies the risk. Furthermore, study design and the general validity of research findings will need evaluation.

Many agencies and programs could synthesize information. Examining the literature available on a particular technology could highlight the need for further studies in certain areas. Thus, additional studies could appropriately be conducted by the same program

that identifies technologies needing assessment. Wherever this function is performed, it should be open to the public and other parties of interest; it also should have public and professional visibility.

Alternative D-1: The task of synthesizing information could be undertaken by the same commission that identifies technologies needing evaluation (Alternative B-1). The advantage associated with this option is that such a commission would be involved in developing information as a result of trials it stimulated. One disadvantage of this alternative is that such additional responsibility would necessitate the increased capability of staff and advisory committees. Also, such a commission might have little credibility with the practicing community.

Alternative D-2: The Institute of Medicine could be asked to undertake this task, in addition to identifying candidates for assessment. The same advantages found in Alternative B-2 would also apply here.

Alternative D-3: NIH could undertake the task of synthesizing safety and efficacy information. NIH already has the largest extant activity in this area and has begun to use the mechanism for developing consensus effectively in at least one area. However, NIH has shown little inclination to make judgments that could be used by regulatory agencies.* Perhaps NIH could continue to develop consensus in areas in which little controversy exists and in which consensus could have immediate benefits, such as that of diagnosis and treatment of hypertension.

Alternative D-4: Agencies involved in technology development could also synthesize the information derived from trials. One disadvantage concomitant with this option is the diffusion of the function among numerous agencies. The disadvantages mentioned directly above in Alternative D-3 also would apply here.

Alternative D-5: FDA could undertake the performance of this task. It already has extensive experience synthesizing and evaluating information submitted by drug and device manufacturers and by physicians. It also has a mechanism for forming expert committees and using outside consultants which would be desirable and applicable to this alternative. However, FDA is basically a regulatory agency and may not be able to attract the scientists necessary for regulating procedures. Again, FDA's negative image with the practicing community would hamper its work.

Alternative D-6: The Office of Health Practice Assessment (OHPA) could undertake the task. OHPA already makes synthesis decisions for the Medicare program. Given adequate resources and access to appropriate experts, it could accomplish the task of synthesizing safety and efficacy information. However, OHPA currently lacks credibility with the practicing community and lacks expertise and access to the information required to complete the task.

Alternative D-7: A new Federal agency could undertake the entire task, including synthesis. (See Alternative B-6.)

*NIH does provide some information, in the form of judgments or recommendations, to agencies such as the Food and Drug Administration. However, the 1977 Department of Health, Education, and Welfare technology management study concludes that the needs of regulatory agencies remain generally unfulfilled.

SECTION FIVE: DISSEMINATING INFORMATION

Synthesized information—regardless of how valid, understandable, or relevant—is of little value if it is not disseminated to those individuals and organizations which need it. This task is more complex than it seems. The agency responsible for such dissemination must not only have access to the synthesized efficacy and safety information, and any any other relevant information, but also must develop, improve, or expand methods of communication to appropriate parties, identify those parties, evaluate the effects of its actions in terms of information conveyed, and perform other related tasks.

Alternative E-1: NIH could refine and expand its dissemination efforts. That agency is one of the most active in disseminating information; and in addition, it contains the National Library of Medicine. However, NIH is reluctant to expand its role in this area, particularly in regard to practicing physicians and health care delivery-related information, partly because of budgetary constraints.

Alternative E-2: This function could be assigned to the Federal agencies involved in testing or synthesis that already perform the dissemination task to a limited degree. The utility of increasing activities by all those agencies, however, would be qualified by at least three factors: parties in need would receive information from a multitude of sources; the function might require a degree of talent, skill, and technique development that many of the agencies could not attain; and many of the agencies do not have the necessary contact or credibility with the parties who need the data.

Alternative E-3: A new Federal agency, as described in Alternative B-6, could be given the funds and personnel for this task. A close working relationship with NIH would have to be established.

Alternative E-4: Instead of assigning the task to a new agency, either one created to perform the dissemination task or one created to perform alternative tasks, a new office perhaps could be developed either at the level of the Assistant Secretary for Health, HEW, or within an existing Public Health Service (PHS) agency. Presently, there is no focus within HEW for health professional information dissemination as there is now for consumer information. Placing a new office at the Assistant Secretary level would have the advantage of proximity to the National Center for Health Statistics. In addition, it would be at a level high enough for access to information and resources of PHS agencies, particularly NIH. It may also facilitate communication with the Health Care Financing Administration. A disadvantage of a new office would be its having to start with little credibility or few contacts with many of the parties who need the information. Also, functional conflicts with NIH would have to be anticipated as in Alternative E-3.

USING INFORMATION

This report has primarily addressed a specific problem: the lack of accessible, reliable, information on the safety and efficacy of medical technologies. The mere availability of such information, however, does not assure the efficacy and safety of medical technologies currently in use. The development and dissemination of efficacy and safety information leads to a fifth step, namely, the application of such knowledge.

As illustrated in chapters 3 and 6, many Federal programs use, or could use, information regarding efficacy and safety. According to health planning legislation, ap-

Mr. SCHEUER. Does efficacy mean cost-effectiveness, or does that just mean that it works at any price?

Mr. BEHNEY. It's not the former.

We spent a lot of time defining it rather intricately because of the possible medical uses of the report, but, essentially, what it comes down to is the medical benefit provided by technology, and the use of certain criteria to measure it.

Mr. SCHEUER. Are they medical?

Mr. BEHNEY. Yes.

Mr. SCHEUER. The characteristics of cost or health output units per dollar, whatever, is not factored into this, I take it, then?

Mr. BEHNEY. No; it's not.

Incidentally, the Office of Technology Assessment is taking a proposed project to the congressional board that oversees us, next month, for a technology assessment of the decision technology, if you would like to call it that, of cost-effectiveness analysis and health care. We view it as a technology because it is a social technology for decisionmaking. We can examine the need for it, and, if used widely, what type of implications might arise from its use.

Mr. SCHEUER. When you say "it," describe "it".

Mr. BEHNEY. Cost effectiveness analysis as we see it at this point. And part of the reason for studying this is because so many people use it in so many different ways there is no real handle on exactly what it means. It is the type of analysis which you use to compare alternate ways of achieving a specified change, or specified goal, and compare the cost of those. It could be financial cost or it could be human and financial cost, or social cost. You just have to define the units.

Mr. SCHEUER. When would you be completing that report?

Mr. BEHNEY. If approved by the Board, the study is slated to take about 18 months, but during that period we would have several intermediate products, or we plan to, that would deal with the state of the art or methodology of cost effectiveness.

Mr. SCHEUER. .That's how you do it?

Mr. BEHNEY. How you do it; how well you are able to do it and get useful results at the present time or in the foreseeable future. Also, we would look at what cost-effectiveness analyses have been done and what effect they have had on policy decisions. For example, there was a rather formal cost-effectiveness analysis, as I understand, performed on renal dialysis. But the political process, as was pointed out earlier, is really the ultimate decisionmaker for large-scale resource allocations, such as that involved in renal dialysis.

I believe we could have a situation where we have a very good analytic tool which is not realistic in certain situations because it wouldn't fit into the actual decision processes.

Mr. SCHEUER. Could you give us the specifics of how the cost-effectiveness study of renal dialysis came out, and how the political process affected that one way or the other?

Mr. BEHNEY. I couldn't give specific details, but we could provide them.

Mr. SCHEUER. If you would provide them it would be very helpful.

Mr. BEHNEY. Surely.

[Requested information may be found in the addendum to Mr. Behney's testimony].

Mr. BEHNEY. A lot of talk has taken place today about incentives versus research, or fiddling around with the state of our knowledge about the benefits, the cost-effectiveness, and the risks of specific technologies or specific programs as opposed to major changes in the incentive system that would be the manner in which we could change the behavior of physicians and the behavior of hospitals.

I'm not appearing here as an expert at all on changing the system. OTA has not fully studied that type of issue. We have concentrated on more technological issues, though we have discussed using cost-efficiency calculations for reimbursement of technologies.

In other words, you figure out the most efficient manner in which the technology can be used and what it would cost to use it that way and the circumstances that a hospital would encounter, and your reimbursement rates would be based on that.

Mr. SCHEUER. Reimbursement rate is a particular kind of a incentive. Right?

Mr. BEHNEY. Right.

Mr. SCHEUER. So it seems to me, if you are going to perform that function fully, you ought to describe a whole array of available incentives to induce hospitals to adopt cost-efficient and cost-effective means of delivering health services. I would hope that OTA would be considering a whole array of possible incentives as well as disincentives for health care technology that is cost inefficient.

Mr. BEHNEY. We have indirectly. We have never been requested to do that as a specific study.

Mr. SCHEUER. Well, why don't we request you. We will discuss with you the possibility of making a formal request.

Mr. BEHNEY. All right.

I was giving that as an example. We have spent some small time examining a few specific incentives. In general, we have not.

I wanted to point out that even if we successfully switch the incentive structure so that there is more of a tendency to keep costs under control, the research side of it would remain just as important beause just as we now have incentives that bring about inappropriate use, which lead to high—there might then be incentives leading to lower costs, which could bring about a sort of flip-flop inappropriate use also, particularly for poor people and elderly people who are served by programs under the control of the Federal Government. These people might, earlier than those under other types of medical services, feel the effects of basing decisions on the new incentives.

So the data that we need to bring about appropriate use, or to get some idea of what appropriate use of a technology is, would be just as imprortant under the new incentive system.

I think it would be a combination effect, so that programs, such as the Office of Health Technology, whether HEW's version or the congressional version, or some other version, would retain its importance and its usefulness apart from changes in the incentive system.

I will try to summarize very quickly the report that we have just put out on the Efficacy and Safety of medicial technologies. It was requested by the Senate Committee on Human Resources. All of OTA's studies have been requested by committees of the Congress.

Mr. SCHEUER. And they never requested you consider the cost implications of these emerging technologies?

Mr. BEHNEY. We have a request now for the cost-effectiveness study. And I think it was 4 years ago that we received a request that was related to cost of medical care; but not directly to efficiency or cost-effectiveness.

The Office has received many more requests than it could undertake. And that earlier, 4-year-ago study was not undertaken.

Mr. SCHEUER. I thought you said a few moments ago that you had never been requested to do a study of the cost-effectiveness of new medical technologies.

Mr. BEHNEY. That's right. I meant until this proposal which we are now going to the board with on October 3.

Mr. SCHEUER. And that will consider cost-effectiveness?

Mr. BEHNEY. The study is going to be on cost-effectiveness.

I believe I meant that we had not been requested to study broad incentives.

Mr. SCHEUER. Incentives, yes. Why don't we have some discussions with them and maybe they can inject the question of the array of incentives as part of that study. OK?

Mr. BEHNEY. Yes.

Mr. SCHEUER. We will be in touch with you. It seems to me that that should be an integral part of your study.

Mr. BEHNEY. I think that it would.

I will try to be very brief on this; it was conducted by the staff of OTA, but we received large amounts of expert advice from an outside advisory panel, which we use on most of our studies. Dr. Lester Breslow, the chairman of our panel, will be appearing before you tomorrow.

Efficacy and safety may be viewed as the direct medical benefits and risks of a technology. You can measure these concepts, but you should keep in mind that they are extremely complex, and the measurement of them has to be very carefully done, and it's very intricate.

Efficacy can be measured separately from safety, but it's also important to keep in mind that appropriate use of a technology occurs when the benefit, the medical benefit, is commensurae with risks, since no, or very few, technologies are totally riskless. What you would be looking for would be a technology whose risks are acceptable, given the benefit you can receive.

The people and organizations who use information on efficacy and safety are just about anybody involved in the medical-care system, including patients, physicians, researchers, regulatory and reimbursement programs, health planning, quality assurance programs.

And we concluded in the report that assessment of efficacy and safety is an extremely important starting point in the evaluation of the overall use of a technology, but that other additional criteria will judge its overall social use.

Some of those listed in the report are, in fact, possible social implications and ethics, the polictical process, legal process, psychological effects. Also, the report points out cost-effectiveness, so we have mentioned this in here.

Mr. SCHEUER. There are some profound ethical considerations here. I don't know if you were here earlier but we discussed some very perplexing questions.

Mr. BEHNEY. I agree. The same type of questions similar to those which may come up in decisionmaking based on cost-effectiveness criteria, exactly.

Nobody knows the exact proportion of technologies which have or have not undergone adquate evaluations of efficacy and safety. It's an impossible task to come up with an exact figure. We examined literature, we found estimates that perhaps only 10 to 20 percent of medical and surgical procedures have had their efficacy and safety demonstrated by well-controlled evaluations.

That, again, is not a way to get at the exact figure, but we sought consensus, and we received one from our advisory panel and from experts from the executive branch, that we consulted, and from many outside experts other than our panel that we consulted with, that there were, indeed, a significant number of such inadequately assessed technologies

This, of course, has great significance for the quality of medical care, because we are dealing with medical benefit and risks. But it also moves into the cost of medical care, because, obviously, the cost is not necessary if it is an unnecessary procedure.

Some of those technologies in current use, about which there are serious efficacy and safety questions, would be respiratory therapy and electronic fetal monitoring.

We used a base of evaluation where, much like the technol- which could lead to premature diffusion of technologies into the system and to inappropirate use of ones already in the system.

Because of our charter, we focused primarily on the existing Federal programs that were supposed to do something about this.

We used a base of evaluation where, much like the technology management study in HEW, we concluded that four basic elements where necessary: identification of technologies needing study; the actual testing or studying of the technologies; synthesising the results, and then disseminating those results to appropriate parties.

We found numerous shortcomings, including the one pointed out earlier, that there really is no coordinated system. There still isn't.

These findings have been generally known since early drafts of our report and since the HEW study.

I think there is a lot of interest now in putting together a coordinated system, but as of this time there is none.

I won't go into each of the four phases, except to point out that the identification phase is particularly important, identifying which technology is particuarly important, because we cannot study every aspect of the efficacy and safety of every technology.

Mistakes made in that phase lead to inappropriate use of testing funds, or less than optimal use of testing funds. It means that we don't have information to synthesize and disseminate. We don't have the needed information to synthesize and disseminate because

we have not in the beginning of the process decided which are the technologies most in need of study. So I think that is the critical phase of the four.

I would also like to mention that the phrase "prudent prerogative of the physician" was used. And I would like to point out that I don't think that that has ever been accepted as a total freedom. Prudent prerogative means that the physician has operated within certain bounds. He has not been able to widely use a drug that FDA would not let onto the market; therefore, there have been ethical and legal restrictions on that.

So we are not talking about all of the sudden telling him he doesn't have total freedom. What we're trying to do is improve the information base so that his prerogatives will be based on more valid reasoning about when to use a technology. In some cases that would just be an information base; in other cases it might take regulation; and in other cases it may take incentives to use the available information.

Mr. SCHEUER. It goes a little more than that, doesn't it?

I mean, as Mr. Miller used it in the last sentence of his testimony, it was just sort of a little peroration, so I don't know how seriously Mr. Miller intended us to take that last sentence, because a great deal of his testimony was taken up with describing to us how we have to shift some of the responsibility for making decisions on cost away from the physician to the administrator of the hospital.

But aren't we doing more than giving the physician information on how to make proper decisions? Aren't we really saying that there does come a point in time when the hospital administrator is going to tell him, instruct him, or request him, to make decisions where the cost element—or a cost-benefit element, has been provided by the hospital administrator, which may veto the prudent prerogative of the physician?

Mr. BEHNEY. I think we are talking about that. We are especially talking about how far that would go.

The point I was trying to make is that we have always taken away some of that prerogative. And what we're talking about now is a much more formalized way to do that; and whether is simply on efficacy and safety information, or whether it's on cost-effectiveness, and whether that takes place by shifting the prerogative to the hospital administrator, which in some cases I think happens—some hospitals often do a cost-effectiveness study and find the most cost-effective circumstances under which to do certain diagnostic tests and that becomes hospital policy—so that's happened.

But we are not necessarily talking about a possible expansion and a possible institutionalization that is perhaps government mandated. That, itself, is an ethical question. It's a political science, ethical, and philosophic question that's being forced upon us by the rising of costs.

Mr. SCHEUER. We've pretty much crossed the Rubicon, don't you think, in informing physicians that they are no longer going to have the whole say in the matter and that society is going to impose upon them some restraints based on costs, some restraints on their prudent prerogative of making decisions?

We have pretty much come to that, haven't we?

Mr. Behney. I believe we have. And now I think we have to figure out the best way of going about doing this.

Mr. Scheuer. Right. That's what these hearings are about.

Mr. Behney. I would also like to say that while the study I refer to has been about assessing the efficacy and safety of medical technology, the medical benefit, the process and the shortcomings identified in it, I think in most cases also apply to these other types of studies that you can do—the standard-setting; the cost benefits; the cost-effectiveness; and social impact—it is perhaps a generalizable study from that standpoint.

That concludes my remarks. Thank you.

Mr. Scheuer. Well, I thank you very, very much.

Mr. Behney. We appreciate your testimony, it was very thoughtful and very useful to us. Dr. Wells?

Dr. Wells. No comment.

Mr. Scheuer. Dr. Murray?

Dr. Murray. I have too long a list to take the time at the moment. Since Mr. Behney is just up the street, if we can have the prerogative of submitting any new questions and having him answer in writing, it would save time.

Mr. Scheuer. Very good. So we may submit some questions to you, and, hopefully, we will get the answers in time for our printed record, and we will also confer with you informally about cranking the questions of incentives in to your study.

And when we get your informal thinking on the subject, perhaps we will then proceed formally to get in touch with the various Congressmen and Senators involved in that process and see if we can get them to agree to adding the question of incentives and disincentives to your study.

Mr. Behney. Thank you.

Addendum to Statement of Clyde J. Behney

In 1967, a cost-effectiveness analysis of renal dialysis and kidney transplantation was issued as part of the report of the "Gottschalk Committee." This committee, established by the Bureau of the Budget, was to advise the Bureau on government-wide policy toward dialysis and transplantation. The analysis indicated that transplantation was more cost-effective than home or facility dialysis, and that home dialysis was more cost-effective than facility dialysis. The report recommended a national program to provide facilities and financing to all patients for whom dialysis and transplantation were medically indicated. The estimates of the probable cost of this program were, as an example, $237 million for fiscal year 1975.

An interesting point concerning the relationship between cost analysis and the policy or decisionmaking process is illustrated by the fact that the Gottschalk Committee was not asked by BOB to do a cost-benefit analysis but rather a cost-effectiveness analysis. Cost-benefit would have involved valuing the benefits (increased years of life) and that, analysts have suggested, was not seen as an appropriate role for a committee of experts.

Congress received other estimates of the cost of a national dialysis and transplantation program. In considering the 1972 Social Security Amendments establishing Medicare coverage for nearly 90 percent of victims of end-stage renal disease, Congress was given an estimate of $250 million per year as the cost.

Actual experience with the Medicare coverage, however, has shown these estimates to be considerably lower than incurred costs. The Health Care Financing Administration has estimated that the annual program costs are $600 million and may reach $1.9 billion by 1987. Further, we cannot dismiss this wide disparity between estimated and actual costs as being entirely unpredictable. Shortly after enactment of the 1972 amendments, the Administration produced estimates that turned out to be much closer to experience. Added to the relatively low level of both executive and legislative branch debate concerning the implications of the Amend-

ments, the above facts have convinced many observers that costs were not the deciding issue, but that a combination of political, moral, and force-of-events considerations led inevitably to passage.

Mr. SCHEUER. Thank you very, very much.

We will now recess our hearings until tomorrow morning at 10 o'clock in this same room.

[Whereupon, at 1:25 p.m., the subcommittee adjourned, to reconvene at 10 a.m., Wednesday, September 27, 1978.]

TECHNOLOGY AND THE COST OF HEALTH CARE

WEDNESDAY, SEPTEMBER 27, 1978

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING, ANALYSIS AND COOPERATION,

Washington, D.C.

The subcommittee convened, pursuant to notice, at 10:45 a.m., in room 2325, Rayburn House Office Building, Hon. James H. Scheuer, chairman of the subcommittee, presiding.

Mr. SCHEUER. The DISPAC Subcommittee's second day of hearing on Health Technology will now commence.

I apologize for the delay occasioned by the rollcall vote. I hope we don't have any more of them, but one never knows.

Dr. Cohen, your statement will be printed in full in the record at the point at which you commence testifying. What I hope you will do is chat with us informally for 10, 12, 15 minutes and not only hit the highlights in your testimony, but give us some of your views on this very important subject.

Now, I will turn you loose.

[The prepared statement of Harold A. Cohen, executive director, Health Services Cost Review Commission, State of Maryland follows:]

STATEMENT OF HAROLD A. COHEN, EXECUTIVE DIRECTOR, HEALTH SERVICES COST REVIEW COMMISSION, STATE OF MARYLAND

EVALUATING THE COST OF TECHNOLOGY

Mr. Chairman, members of the committee, the rising costs of hospital care can be attributed to many factors. The casual emphasis given to any one factor—such as technology—depends upon your model or theory of how the hospital sector works. My model of that sector assigns almost no causal responsibility to technology for the rise in hospital costs. Rather the increasing cost in real nonlabor hospital expenditures per capita follows from the structural defects in the hospital market place. The unique aspects of the relationship between capital and labor in the hospital market follow from the inappropriate incentives existent in the hospital sector.

The most important contributor to the high cost of hospital care is the use rate. The average utilization rate in days per 1,000 for the United States is over 1,200. For California it is about 950, but for almost 2,000,000 members of the Kaiser-Permanente prepaid group practice living in California it is about 425 (Zaretsky). Technology does not contribute to these differences—the same techology is available to all. The basic differences—aside from population or demographic differences—are medical practice and the incentives associated with fee-for-service medicine versus prepaid medicine. A great deal of evidence supports the contention that use rates are significantly higher when doctors are paid more to do more. (Gaus, et al.)

Consumers are heavily insured. Ninety percent of hospital revenue comes from third party and other insurance mechanisms—insurance which often encourages people to seek hospitalization rather than less expensive but perfectly adequate

institutional settings and to seek physicians rather than less expensive but perfectly adequate practitioners. The normal market pressure of buying only when the increased value to the buyer is greater than the increased cost to the buyer is missing. This is both because the buyer lacks information and relies upon the above mentioned physician and because the out-of-pocket cost of health care is small relative to the actual cost.

This is further compounded, as Alain Enthoven has discussed, by the tax laws. Expensive health insurance packages are underwritten by making fringe benefits non-taxable income. If a typical worker believes a $1,000 health insurance benefit is only worth $800, the worker would still prefer the insurance package to another $1,000 in wages. This is because the after tax increase in income from the $1,000 would be well less than $800. The differential application of social security taxes on employers wages and fringe benefit payments also gives the employer an incentive to overbalance pay via fringe benefits.

Not only does the public have inadequate incentives to shop for less expensive health care, it has inadequate incentives to seek health—or inadequate penalties for trying to avoid sickness. The principal Federal taxing mechanism to fund our health care system is social security taxes—a tax on work. I know of no study which suggests that working (other than OSHA covered situations) increases the probability that one will need to use health services. Yet Fuchs, among others, in a book entitled who shall live demonstrates quite strikingly the effects of life style upon health status. The majority of people admitted to the Maryland Institute for Emergency Medicine have significant amounts of alcohol in their blood. This suggests a more appropriate funding source than work. Cigarettes, speeding and other illness-causing life styles should be paid for by the person who chooses them—not subsidized by others.

Since the largest chunk of our health care expenditures is focused on hospitals and because most of our expensive technology—the half-way (or treatment?) technologies—are located in hospitals, we must look at how the system encourages hospitals to act—what practices are financially rewarding.

How does the hospital respond to physicians and patients who want to consume too much hospital care? About the same as how the corner candy store acts when your child wants to buy too much candy. They oblige and cheer as their cash flow and financial position is strengthened.

It is important to understand why hospitals are financially more sound when they are full. A brief discourse on the medicare payment system—how they dispense those taxes on working—is appropriate. My purpose here is to demonstrate that Medicare's reasonableness criteria reward excessive use. Courses are offered in ways, other than increased efficiency, to reduce a hospital's routine costs per day as calculated by Medicare. Only two of those concern us here. The first is to perform more ancillary and outpatient services. This will result in more overhead costs being allocated away from the routine inpatient service. Remember, Medicare has no screen on ancillary or outpatient costs. Shifted costs will be paid. The second is simply to have more patient days. Given that a significant proportion of a hospital's costs are fixed within the year, more days—whether medically neceasary or not—will reduce average cost as the fixed overhead is spread more thinly. The commission is also guilty of misincentive in the efficiency review method but it is being altered—in large part with money from the health care financing administration.

Given this incentive to encourage high occupancy, hospitals "advertise" to encourage use of their facility. They do not advertise in the normal sense—they compete for attending staff. Patients generally go to where their physicians have privileges. Few patients pick physicians because of the hospitals at which they have privileges. Thus, the competition is for attending and admitting staff rather than for patients. Hospitals do not compete for attending staff by placing advertisements on television. The normal method is by providing perquisites. These perks may include house staff (both physicians and otherwise) to do much of the work (at Blue Cross expense) that is traditionally included in the attending physician's charges (at Blue Shield expense), doctor's office buildings built with hospital endowment funds and rented at rates far below the commercial rental rate—as if people gave money to hospitals in order to help "financially troubled" physicians and society made hospitals exempt from property taxes because they wanted to help reduce physician office costs—and by providing physicians with the equipment they want. Thus, we see that buying high cost technology is, in part, a symptom of the competition for attending staff which, itself, follows from the need to attract patients. Of course, from a social perspective, we do not care what hospital the physician chooses. The competition—which only thrives in an atmosphere of excess beds—is almost entirely wasteful from the social perspective.

Hospitals are on the receiving end of the heavily insured public. Just as 90 percent of hospital costs are not out-of-pocket costs to consumers, about 80 percent of hospital costs are not "out-of-pocket costs" to the hospital. A competitive business sells its goods in a market which dictates the price. Any additional expenditure in producing the good or service being sold decreases the profitability of the business dollar for dollar. The typical hospital in the United States gets "Reimbursed" from medicare and medicaid on the basis of their costs. In many states, Blue Cross pays on the basis of costs—in others on the basis of charges. Either way a hospital's revenue can be automatically increased by at least 80 percent of the cost of any expenditure—subject to the above mentioned reasonableness limit—including technology. Indeed, cash flow is better if the equipment is leased rather than purchased. Lease costs are generally paid in the year they occur. A purchase is paid back over a period of years according to the whims of depreciation accounting. The typical piece of fixed equipment has a 10-year life for depreciation purposes.

All this is, of course, not overlooked by the equipment industry. They know that hospital's cash flow is better if they lease—and they make lease terms very profitable for themselves. They also know that leasing can be defended successfully if technological advance is likely to make the product "obsolete" before the 10-year depreciation cycle is up. This puts a premium on developing improvements and convincing hospitals—which may want to be convinced—that their old piece of equipment is obsolete. "Obsolete" in the medical technology business often means "older", less fancy, and poorer quality for less money. It almost never means less efficient in the economic sense. Is it purely a fiction of my imagination that hospitals which wait 20 minutes for a physician to read an EKG that takes 45 seconds to take might buy a new EKG machine that takes 20 seconds?

The other technology—or equipment—problem that follows from the reimbursement system is that the hospital industry is about the only industry where labor and capital are almost always seen as complements rather than substitutes. That is new equipment calls for more—or more highly paid—labor rather than replace labor. Costs go up both through technology cost and added labor cost. Even after all the "boom" in technology the average hospital in Maryland—which costs over $170 per day—has a cost of about $6 for equipment, building, lease payment, and interest expense. This compares to $100 a day cost in salaries, wages and fringe benefits. Even with that showpiece of modern technology—the CAT scanner—the most important element of the cost is labor cost especially when the radiologist's fees are included. In fact, the radiologist's fees alone are equal to or greater than the machine's cost taken alone.

All this shows that the cost of technology can not be assessed separately. The problems are more pervasive than that. Nevertheless, from 1974—1976 hospital cost per capita in the United States rose 7.9 percent faster than the cost of living. This 7.9 percent has been broken down by McKinsey & Co., Inc. as follows:[1]

1.6 percent hospital wage increases above cost of living.

1.7 percent more labor per patient day equivalent.[2]

4.4 percent real nonlabor cost increase per patient day equivalent.

0.1 percent more patient day equivalents per capita.

That 4.4 percent for nonlabor is largely the supplies and equipment associated with doing more tests and other ancillary activity—"creeping intensity"—per patient day.

The real question is, "what is the public getting for all this expenditure?" There are serious questions in the medical literature about the medical benefits of intensive care units, bypass surgery, body scans, etc. The Federal Drug Administration will not allow a drug to be sold—costing $1 out of our pockets—unless it can be shown to be curative or relieve symptoms. Our hospitals spend millions on technology without any such proof.

The solutions to the improper incentives in the medical market place are not at all centered around the hospital. Physicians' decisions generate about 90 percent of hospital costs and we must strive to change the way physicians evaluate the necessity and appropriateness of the way they provide medical care. The key areas for change appear to be the nature of medical education and the nature of the physician payment system.

More appropriate incentives for consumers could be brought about by redesigning insurance packages—especially so that high cost treatments are not less costly out-of-pocket than low cost treatments—and by a tax policy and insurance package which has people contribute toward health care according to life style factors and

[1] Components do not sum to total due to rounding error.

[2] A patient day equivalent includes a weighting for outpatient activity.

which makes health insurance compete on more equal footing with other forms of expenditure or compensation.

I would like to close with brief observations regarding comprehensive health planning reform and health care financing reform. The comprehensive health planning act is an economists's nightmare. Local people who get the benefit from any capital project—including new technology—decide whether they should have access to it. Their decision that they "need" it triggers an unlimited flow of dollars into that area to pay for the costs. While planning agencies must consider "financial feasibility", the fact is that in a cost based reimbursement world, if the costs of anything planners approve are paid, then anything they approve is financially feasible. We have a nonoperative constraint due to circularity. This must be broken. Planners must either be given a fiduciary stake in what they approve (such as having communities taxed according to their local health costs or block granting health along with other social programs) or else the blank check must be taken away (such as title II of the President's Cost Containment Act).

The Health Care Financing Administration should move toward prospective reimbursement where hospitals have fixed budgets including equipment. Section 223 (the reasonableness tests which Senator Talmadge would expend) should not be applied so as to encourage excessive use. Further, the Health Care Financing Administration should encourage intermediaries and State Title XIX programs to help eliminate excessive duplication of high cost technology by selective contracting with low cost providers. We do not let recipients of any other welfare program select freely—without financial constraint—among all providers. It is a luxury we cannot afford in the health care field.

In addition, or instead of the above, Congress could at least develop a national health policy which would give direction and support to cost containment efforts. For example, Congress could express its opinion that aggregate expenditures on acute general hospitalization should not rise any faster than personal income—or any such expression of overall constraint. Clearly, without major structural change we can not expect the market or the regulators to reach a rational outcome. Local health planning agencies, by law, have to consider access and cost containment. Since they get the benefits of increased access and others pay the costs, is it surprising that access almost always is primary? Professional standards review organizations, by law, must consider masters of quality and cost containment. Since physicians are taught to revere quality and equate it with high technology and since high technology medicine is more lucrative to the medical profession it is surprising that O.P.E.L. found little if any P.S.R.O. contribution to cost containment?

If Congress wants cost containment, it must stop giving mixed messages to the bureaucrats to whom it delegates program operation.

Having cheered you up with this delightful picture of the medical technology market place—indeed of the medical marketplace in general—I would like to close with an excellent quotation which puts the problem in an interesting perspective. After all, expenditures on new technology represent alternative opportunities foregone. When we talk about expanding the health care system we should think in terms of what alternatives we, as a nation are giving up.

Let me give you a more specific idea of opportunities foregone. Clifton R. Gaus and Barbara S. Cooper in a paper entitled Technology and Medicine: Alternative for Change" note that "medicare spent $4 billion in fiscal year 1976 just for technology that has been implemented since 1967". They then proceed to provide some alternatives:

"The magnitude (of medicare's $4-billion (expenditures for new technology) becomes even more striking when contrasted with other federal spending for the aged. In fiscal year 1975, the Federal Government spent just $26 million for dental services for the aged, about $185 million for drugs and drug sundries, and only $7 million for eyeglasses, hearing aids, and other appliances. In fiscal year 1976, the aged received in kind Federal benefits of $1.2 billion for food and $400 million for housing. In other words, last year the Federal Government spent 10 times more for hospital technological change than for housing for the elderly. Yet, the housing, nutritional, and other health needs of the aged are critical. A minimum of 3.3 million elderly live below the poverty line: 6 million live in substandard housing: a minimum of 4 million subsist on diets below the lowest acceptable level of nutrition: 18 million need or wear eyeglasses: over 3 million need hearing aids: and 16 million need basic dental care. The point here is that since the Government is not committed to meeting all the needs of the aged, choices must be made. If we had continued providing hospital services to the aged, as they were in 1966, then we could have spent that $4 billion last year in other ways. We could have:

Brought all aged persons above the poverty line, or provided the rent to raise 2 million elderly from substandard to standard housing units: or brought all the elderly above the lowest accepted food budget and more; or provided eyeglasses and hearing aids to all who needed them, and more."

In my judgement no non-primary health care services are as needed as the programs and personal needs we have sacrificed in financing health care.

What do you think?

TESTIMONY OF HAROLD A. COHEN

Dr. COHEN. I thank you very much, Mr. Chairman. Thank you very much for the kind words and for the opportunity to speak to you today. I will summarize, as you have asked.

The question has to do with the cost of technology as it impacts hospital costs. And, as I indicate, the rising cost of hospital care can be attributed to many factors, and the causal emphasis that you give to technology depends upon your theory of how the hospital sector works. My theory of how the hospital sector works identifies technology costs more as a response to what is wrong in the system as opposed to a causal agent in driving up the cost itself.

The most important contributor to the high cost of hospital care is the use rate. And there is a good bit of testimony suggesting that——

Mr. SCHEUER. The "use rate" of what?

Dr. COHEN. The health resources, the number of people, the number of hospital days per thousand, or per capita in the population.

And there is a good bit of testimony suggesting that the major causal factor associated with that is the way physicians are paid. Hospitals are there, many people have suggested, as a workplace for physicians.

On the one hand you have physicians who are paid more when they provide high-technology medicine. And we have patients who are heavily insured without incentives to avoid high-cost medicine.

Mr. SCHEUER. Doctor, let me warn you, I am going to try and pin down and ask you to give us some specifics on these incentives.

Dr. COHEN. Absolutely.

Mr. SCHEUER. I was really most captivated by your written statement, but I am going to ask you as we go through to dot some "i's" and cross some "t's". And if we don't have time to do it today, I'm going to ask you to submit perhaps some extra thoughts for which we will hold the record open, but we are very keen on knowing how you structured incentives into the Maryland system, so maybe as you talk you will give us some details on that.

How do you structure incentives that will attract people to use the system intelligently? How do you create disincentives that will sort of ease them off of silly overuse of the system—how do you structure the kind of incentives that will work intelligently for all people, discouraging overuse, but not be such a disincentive for the elderly and poor persons that they hesitate to go when they really should be going, and not defer going until they really need intensive, high-technology sickness care?

Dr. COHEN. OK.

Mr. SCHEUER. I don't want to interrupt your flow of thought, but I do want to say that we hope to get a laundry list of "how's"—how to do it.

Dr. COHEN. Well, as I say, the hospital is sort of a meeting place of physicians who, on the one hand, are paid by fee-for-service, which is encouragement to provide more medicine. And the way Blue Shield and commercial insurance fee schedules are set, it's to their advantage to be specialists relying on high technology and have that kind of medical knowledge.

On the other hand, we have patients who are very highly insured. Indeed, it is very often that the out-of-pocket cost to the patient is higher when they use low-technology forms of medicine than it is when they use high technology.

For example, it is more costly to a patient out-of-pocket, very often, to have some home care than it is to have hospital care if the hospital bill is paid by their insurance.

Mr. SCHEUER. Or to have outpatient care in the hospital rather than to be socked into a hospital bed on a Friday and have a doctor look at them on Monday morning.

Dr. COHEN. That's absolutely correct. Generally, in almost all cases, it is cheaper to go into an intensive-care unit than to stay on a regular floor and hire your own private-duty nurse, because you have to pay for the private-duty nurse out-of-pocket under most systems.

But in the intensive-care unit, of course, Blue Cross or your insurer will pay because it is a hospital cost then as opposed to a personal service.

Mr. SCHEUER. A decent compassionate doctor who knows the patient is operating on financial constraints, might say "look the guy can't afford a private-duty nurse so we will put him in intensive care and he won't be burdened by that".

Dr. COHEN. I think that is absolutely correct.

Consider: How do we finance a health care system? There are two aspects of it.

One is doctors make more money if they provide more care. Patients have no major incentives to avoid that, other than not liking to be cut up and kept in a hospital, but they don't have any financial barrier in many cases.

Mr. SCHEUER. We should put in incentives to stay well, and disincentives to get sick.

Dr. COHEN. Well, along those lines, I would suggest that one of the things most interesting is that the major Federal program—there are two, of course, but the largest one is Medicare.

Medicare is financed basically by a tax on work. I mean, that's how I would describe the social security taxes. Whereas, except the OSHA-related things, there's relatively little evidence that working makes people sicker.

On the other hand, as you have suggested, Victor Fuchs has pointed out that there are many lifestyles that increase the probability that people will use the health-care system. And that suggests that it might be much more rational to——

Mr. SCHEUER. Excuse me. We are being joined by a very distinguished colleague, Tony Beilenson, of California.

We were just discussing one of the world's great experts in health economics, Dr. Victor Fuchs of—where in California—Stanford?

Dr. COHEN. Stanford; yes.

At any rate, the logical followthrough of that argument is that it makes more sense to generate money for the health-delivery system, at least in part, from those lifestyles which increase the probability of using the health-care system.

To give you an example, the most costly medicine in Maryland is that provided by the Maryland Emergency Medical Service, very high technology, very costly, very capital and labor intense.

Maybe just the room charge is $500 a day for that service, and we have helicopters going all over the place, to pick up patients.

It does save people's lives. I would much rather pay $500 a day room charge and know I am doing something than $200 a day and not know if I'm doing anything.

But what I was getting at is that they have done a study and found that close to 50 percent of the patients admitted have significant amounts of alcohol in their blood at the time that they are admitted.

Mr. SCHEUER. And they are admitted mostly from accidents, severe accidents?

Dr. COHEN. Mostly, yes; from a lot of severe automobile accidents, and there's no way of knowing how many of the other 50 percent are there because they were injured by people who in turn had alcohol in their blood.

But I do know at least half had significant amounts of alcohol in their blood, which suggests that might be an appropriate form of raising funds, as might an assessment on other things that also increase the probability of needing emergency care, as when someone is found guilty of speeding. Right now most of the penalty, at least in Maryland, is because the person is using up more gasoline than he would like them to use up.

And there are penalties assessed, but no one takes into account the increased probability of generating health uses.

Tobacco is a clear one.

With regard to diet, I think it would follow that if we had dental insurance it would make sense—you know, we could structure what foods it would make sense to have taxed.

I suggested that some companies might, for example, have 80-percent coverage for their employees and 20-percent coinsurance. I have suggested that they might, without raising the contribution from anyone, simply offer that if their employees would sign an affidavit saying they don't smoke and have an annual physical whereby they are shown not to be more than—whatever—20 pounds overweight that the company would pay 90 percent; just give them something extra that the contract does not call for. Being that they are group rated it would probably save them money in the long run if they would encourage people to change their lifestyles in that way

With regard to the way we pay hospitals——

Mr. SCHEUER. Just one moment.

On these disincentives for health-threatening lifestyles, let's assume that Congress liked the idea of having people pay for lifestyles that are health threatening.

How would you structure those disincentive payments? How would you do it?

Dr. COHEN. I think it's very difficult to imagine. Personally, I would probably have an excise tax or something of that sort on cigarettes.

Mr. SCHEUER. We do have now. Are you saying raise the excise taxes substantially?

Dr. COHEN. Yes, and earmark the money for the health fund as opposed to——

Mr. SCHEUER. And alcohol the same thing, I presume?

Dr. COHEN. Yes.

I don't know exactly——

Mr. SCHEUER. Aunt Sara's cake mix?

Dr. COHEN. I was going to say that I don't know how to handle the obesity problem or whatever.

I don't think you should simply tax sugar or things that generate health needs.

On the other hand, I think it makes much more sense in that case to try to structure a coinsurance payment; that is to say, everyone pays the same premium, but your share of your costs go up if the way that you eat, for example, tends to increase the likelihood that you use the health delivery system.

Mr. SCHEUER. Or, maybe putting it a little bit differently, your share will go down, we would give you a reward for not being overweight, for not having signs of alcoholism, drug usage, tobacco use—if you can bring out those things in a medical examination.

Dr. COHEN. I think alcohol and drugs are much more easily handled with an excise tax.

Food, I think you have to handle some other way. And that may well be by comparing body weight to some kind of standard or something of that sort.

The question then is, you now have a hospital where, on the one hand, you have physicians who have an incentive to overproduce and patients who, on the other hand, have incentives, first of all, to go to the hospital where they might otherwise not, and do not have appropriate incentives to reflet on all the social costs of their own lifestyles.

And how does the hospital react? First of all, I would suggest that looking directly at the hospital as opposed to trying to change the incentives on the patients and the incentives on the doctors is to a large extent tinkering on the margin—that the major changes have to do with changing the incentives facing the physicians and patients.

But if we do look at the incentives of the hospitals, the incentives now are such that the hospital acts much like the corner grocery store or candy store when your child comes in to buy a lot of candy; namely, they cheer and realize a nice cash flow while all of this is going on.

And there are many reasons for that; one of which is the reasonableness criteria under medicare, which I believe is to be expanded under the Talmadge bill that is currently being considered. It would be continued in much the same way. That is, a hospital's reasonableness is evaluated on a per-service basis for routine care. That is the way that medicare does it now.

Well, there are basically two ways to reduce your cost per unit for routine care. One is to do an awful lot of ancillary testing; that

is, to do a lot of X-rays, a lot of blood tests, a lot of—you know, all those things other than simply caring for the patients in rooms.

The reason that reduces your cost per day, your routine cost is because of accounting reasons. You simply allocate more of your overhead costs to the ancillary departments.

The other way of reducing your average cost of routine service is to have more patient days, because since there is an element of fixed cost in a hospital, a fairly large element at that, especially on the nursing floor, by having more days for the same amount of nursing service, you reduce your average cost quite considerably.

Mr. SCHEUER. You reduce your average per diem cost, not the total.

Dr. COHEN. Total expenditures, which is the problem, is, of course, increased; but per diem cost, which is what the review is all based on, is reduced.

And, indeed, what that means is that physicians—attending staff—becomes particularly important to hospitals. Hospitals don't compete for patients, they don't put advertisements in the newspapers saying "when you get sick, come to us." What they do, for the most part, is compete for attending staff, because that's who brings the patients to them, and the patients are their life's blood.

Indeed, in Montgomery County, which is right near here, the planners have approved very significant increase in capacity—I think 26-percent increase in capacity—over a period when population is expected to increase by 6 percent. And one hospital, for example, came to us and said they wanted to increase their house staff quite considerably. They also want to build a doctor's office building with endowment funds.

These are the kinds of ways that hospitals traditionally have competed for attending staff. They provide house staff to do for the doctors what the doctors used to do for themselves. And their services are already included in their "usual customary and reasonable" fees, so we have Blue Cross paying the hospital for the house staff, while Blue Shield is paying the doctors for their own service.

We have hospitals which build office buildings, often with endowment funds. And then we have something called generally accepted acounting principles which tends to dominate reimbursement in the hospital field, at least under medicare/medicaid and the Blue Cross plan, where the hospital is exempt from taxes, property taxes; therefore, there are no property taxes shown on the books of the cost of that particular doctors' office building.

If you build an office building with endowment funds you don't have to pay interest. The fact that you lose the interest that you would have had if you had invested that money is not a generally accepted accounting principle. I mean, economists have always recognized foregone interest earnings.

So, again, the books of the particular enterprise would show no interest cost. And so the hospital can say that they're not losing any money, they are covering all their costs. But they are not.

In effect, what is happening is the hospital's tax exemption has been passed on to the doctor. And the interest earnings in the endowment funds have, in fact, been passed on.

I just don't happen to think that's particularly appropriate. And that is only some of the reasons.

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I think the spread of technology, to the extent that it is excessive,—especially some of the high technology stuff, more visible stuff—is largely a matter of competing for attending staff; that in order to get physicians to come to your hospital, it is desirable to have the kinds of equipment that they are used to and that they want, and that they can demand.

Mr. SCHEUER. And you discussed the perks. Perquisites.

Dr. COHEN. And those are the kind of perks that has been provided for attending staff.

So I think it is not that high-cost technology is a cause of it, but rather that it very largely is a result of the way hospitals are paid, physicians are paid, and the public is insured. I think that is basically what I would argue.

Now, let me describe, if I may for a moment, how hospitals earn their money in Maryland. Because Maryland is a unique State. It is the only State in the United States where all payers are paying hospitals based on rates set by the State.

Medicare and medicaid pay all the hospitals according to rates set by the Commission for which I work.

And all the large hospitals in Maryland are not paid based on a matter of how many days of care they provide, or how many tests they provide. Most are paid on their case-mix-adjusted number of admissions.

So whenever a hospital can shorten its length of stay—if it goes to preadmission testing, or goes to home health care followup and shortens its length of stay— the hospital makes money.

Mr. SCHEUER. But under the present system it would be penalized, of course.

Dr. COHEN. Under the medicare system it would either be in jeopardy through the reasonableness criteria, or else it would just be neutral. It certainly would not make any money.

Let me give you another example. As I indicated, the really bottom-line question is total expenditures; it is not cost per unit.

We have a hospital, Lutheran Hospital in Baltimore, whose rates we just increased by 28 percent but their total budget was reduced. That was used as an incentive to get them to go out of certain businesses. They went out of obstetrics, deliver room, nursery, and pediatrics. The fixed costs which those department rates were covering were put into their other rates, so their other rates went up quite significantly, but the total budget of the hospital fell, and the occupancy of the hospital fell quite considerably, if you still include those beds in its capacity.

You might have read a result that was published by Group Hospitalization, Inc., which is Washington area Blue Cross, just recently, in which they compared what had happened in the Washington, D.C., northern Virginia, and the Maryland counties of Prince George's and Montgomery last year. This is for the year ending March 31, 1978. And you might find that result rather instructive.

In Washington, D.C., the cost per day increased by 15.6 percent, but length of stay increased quite significantly. So that cost per admission, according to GHI, increased by almost 34 percent. That's in the District; cost per admission went up by 33.8 percent.

In northern Virginia, according to GHI, cost per day went up by 15.4 percent. The length of stay fell. And cost per admission rose by 9.4 percent.

In Maryland counties of Prince George's and Montgomery, cost per day went up by 5.7 percent. The length of stay dropped very significantly. And so an average patient's bill, that is the cost of treating the average patient in those two counties, fell by 7.3 percent for the year ending March 1978, according to Blue Cross.

I think that shows that something significant can happen. That may have been an unusually good year, and it certainly is not going to continue quite that good because there is an awful lot of new construction that has been approved for the Montgomery/ Prince George's area, but there has been some reduction actually in the cost of health care in, at least, those two counties.

In regulating utilities there is a general theory that utility companies, such as gas and electric companies, are too highly capital intense. This occurs because utility companies are allowed a rate of return on their capital investment, but only a passthrough or current cost on labor.

I would suggest that, in hospitals, the opposite may well be the case due to medicare principles; that there are incentives, under the medicare principles, for hospitals to use labor where capital could do the job more efficiently. Here I am talking more about such things as the laundry, the kitchen, those kinds of areas.

Medicare reimburses hospitals on the basis of historic book depreciation. And we all know that in a period of inflation that, in effect, the hospital's capital is continually eroding when it's being paid historic book depreciation.

On the other hand, if you use labor you get reimbursed for current costs at all time; you get the out-of-pocket cost of what they are paying the particular laborer.

A hospital which knows it can save, say, $100,000 a year by buying a large amount of equipment and firing 10 people may very well not do it, because when it fires those people it doesn't reap any benefit, it's insurers reap the benefit under cost-based reimbursement.

And so I think it would make a lot more sense to have prospective reimbursement for hospitals; that is, just tell hospitals in advance, "this is the amount of revenue you can have". And if the hospital can cut its costs it can keep the savings. If the hospital's cost goes up it's a risk. I think you have to be symmetrical.

If the only way to get hospitals to cut their costs from $100 to $90 is to pay them $95, it makes an awful lot of sense to pay them the $95 instead of continually paying them the $100. And so I think a judicious use of incentives through prospective reimbursement makes sense.

If you allow hospitals to make money if they underspend their budgets, then it is much easier for a hospital which has been historically fat to make money. But the state of the art of identifying the historical cost pattern of a hospital as fat is very primative. So zero-based budgeting would eliminate that problem.

I would call your attention to the fact that perhaps the most prominent advocate of zero-based budgeting in the United States has proposed a hospital review system where you take historical

cost and you multiply by a number, 1.09. I think that is in part a recognition of the fact that zero-based budgeting is very difficult in hospitals.

Mr. SCHEUER. Are you referring to the fellow that lives down on Pennsylvania Avenue?

Dr. COHEN Yes, sir, that's the one.

He has made a big argument for zero-based budgeting. But the hospital cost control bill he introduced says you take their base budget and you multiply by 1.09. Whether that makes sense or not, it certainly suggests that there is not much hope held for zero-based budgeting in the hospital area—at least at this time.

I would mention that we do budget reviews. We compare hospital costs but we don't have standards, absolute standards for efficiency. We just compare hospitals to see which ones are particularly out of line. And that has allowed us to eliminate about 2 to 3 percent of historical cost. There is not very much to be gained there; 2 to 3 percent is pretty good compared to the cost of doing it, it is nothing compared to the amount that hospitals can cut out of their budgets if we give them the incentives to do so.

I think that is the key; giving the hospitals the incentives. And one way of doing that—and it's the way that we do it—is to approve the hospital's budget for the following year—or hospitals' revenue for the following year—they can spend it however they please; if the hospital can get along spending less than that, not only do they keep that money but they continue keeping the money. That is, in the year after that we don't say, "ah-ha, you showed us you can be more efficient so we are going to reduce your target". You say instead, "OK, this is what we approved last year, this is how we measure inflation, so we are going to pump up your revenue constraints according to how we measure inflation." And so the hospitals can continue to make funds until we do the next review, and that might be 4 or 5 years, maybe longer for a particularly efficient hospital.

A hospital that can live within the revenue constraint of the inflation adjustment system, as far as I'm concerned, can get along fine forever. That is, they don't need any bureaucrats telling them what to do, because our inflation adjustment methods allows about 7½ to 8 percent increased cost per admission. And that's about maybe 60 percent of what's happening in the Nation. So if a hospital can live with that, they should be left alone.

Last year, overall in Maryland, hospital cost per admission went up about 8 percent, except in the two counties of Montgomery and Prince Georges mentioned previously. Planners in these counties bordering the District of Columbia made the decision that the people of Maryland should be able to go to Maryland for their health care. One result is an emptying out of many of the hospitals in the District of Columbia. The increased volume causes total costs in Maryland to go up faster than would be the case if the care of many of those people were still provided in the District. But the cost per patient in these two counties has been lowered, not raised. Overall in Maryland, that went up about 8 percent last year. And that, as I say, is considerably less than the national rate.

I think, as far as I recall, I have hit most of the highlights. Having cheered you up with a delightful picture of the medical

marketplace perhaps I can close with a quote from a paper Clifton Gaus and Barbara Cooper, they work for HCFA——

Mr. SCHEUER. What is HCFA?

Dr. COHEN. Health Care Financing Administration. That's down the street, the other way.

Medicare spent $4 billion in fiscal year 1976 just for technology that has been implemented since 1967. Gaus and Cooper list some alternatives, the possible ways that that money might have been used. And this is a quote from those authors:

> The magnitude of medicare's $4 billion expenditures for new technology becomes even more striking when contrasted with other Federal spending for the aged. In fiscal year 1975, the Federal Government spent just $26 million for dental services for the aged, about $185 million for drugs and sundries, and only $7 million for eyeglasses, hearing aids and other appliances.
>
> In fiscal year 1976, the aged received, in kind, Federal benefits of $1.2 billion for food and $400 million for housing for the elderly. Yet, the housing, nutritional, and other health needs of the aged are critical.
>
> A minimum of 3.3 million elderly live below the poverty line: 6 million live in substandard housing: a minimum of 4 million subsist on diets below the lowest acceptable level of nutrition: 18 million need or wear eyeglasses: over 3 million need hearing aids: and 16 million need basic dental care. The point here is that since the Government is not committed to meeting all the needs of the aged, choices must be made.
>
> If we had continued providing hospital services to the aged, as they were in 1966, then we could have spent that $4 billion last year in others ways. We could have: brought all aged persons above the poverty line, or provided the rent to raise 2 million elderly from substandard to standard housing units, or brought all the elderly above the lowest accepted food budget and more; or provided eyeglasses and hearing aids to all who needed them, and more.

In my judgment, our priorities are somewhat inappropriate. And I think that we have to consider whether the nonprimary health-care services are as needed as the programs and personal needs I just mentioned.

In the health-delivery system—and this is questioned largely with regard to planning, I think it is important to recognize we have, in effect, set up a system which says that we will pay for anything someone defines as needed.

That is basically what the planning law does. It says when local people determine that they need something, then we will pay for it.

Planners are to consider two things; one, is need and one is financial feasibility. I defy you to tell me how a project cannot be financially feasible in a cost-base reimbursement world where all the payers pay the cost of anything that the planners approve.

It's circular reasoning. If they approve it, then they get financial feasibility. We say, "OK., local people, you decide whether you need it; you don't have to pay the cost if you decide you do; we will finance that socially for the most part."

So we finance health needs as we perceive needs. We do not finance education as we perceive needs, nor do we finance housing as we perceive needs.

There was a rather instructive debate last night between the two gubernatorial candidates in Maryland; the candidate for one of the parties said we should have a quality level of education, but the level we can afford.

That person's running mate then talked about health care and said all the people should have access to the best quality health care.

I think that is a misconception, or at least I don't think it is appropriate. We should recognize that what we spend on health care is competing with what we may spend for many other social needs. And unless we are ready to meet all of our needs, we should not necessarily say we're going to meet them all in health, but will have to decide what we can afford.

Thank you very much.

Mr. SCHEUER. We thank you very much, Dr. Cohen, for your most stimulating testimony.

I'm going to ask Congressman Beilenson to take over from here and ask some questions. He was Chairman of the committee of the California State Legislature that was responsible for health and, health-care costs. So he brings a great deal of expertise to this hearing.

Congressman Beilenson.

Mr. BEILENSON. Thank you, Mr. Chariman.

Actually, I really at this point don't have any questions. Mainly because I agree with virtually everything that Dr. Cohen has said.

I do want to say that I appreciate his being here and my having been able to listen to his testimony as well as having read his prepared statement.

It is true that when I was back in California I was involved in this field to a certain extent during at least two sessions of the legislature.

We always spoke of Maryland, at that time, as being the only place that had succeeded in pioneering and doing something that—at least trying to do something about these very severe problems. So it is very nice for me to be able to finally meet you personally and find out at least a little bit about the results of your work here in Maryland.

As I said, I really have no specific questions, Mr. Chairman. I am anxious to hear from the other people. I do agree with him.

Mr. SCHEUER. I agree with him, too.

I mentioned before you came in that Victor Fuchs wrote a very short book, about 150 pages, called "Who Shall Live," and it it was my introduction to the field of health economics.

Mr. BEILENSON. I read it at a little inn in Encino 3 years ago.

Mr. SCHEUER. Between the two of them, I think they have said it all.

The question is: How do we get into the stream of commerce.

I'm just going to ask a couple of questions. First of all, OTA is now involved in a look at medical technology. They are looking at its efficacy and they are looking at its safety.

But as I understand it, Dr. Wells, they are not looking at its cost-effectiveness.

They are not including any scrutiny on the question of cost. Is that right?

Dr. WELLS. That was not part of the charter.

Mr. SCHEUER. That is not part of their charter. They are looking at safety and efficacy only.

In terms of all these doomsday decisions that the Congress is going to have to make, these triage-like value judgments, don't you consider it anomalous, to say the very least, that they are not figuring in the question of how much technology at what price?

Dr. COHEN. There is no question about it.

I think, at some point Congress is going to have to make bottom-line health policy decisions, such as should expenditures on health rise faster than personal income and, if so, how much faster? And if Congress makes the decision that we're going to increase medicare—depending on how health is financed—and that expenditures on health are going to only take up so much more of the resources we have, then somehow we have to decide which of those expenditures are not to be realized.

I think it is incumbent upon the Congress to make that kind of policy decision. It should not be left to a bunch of bureacrats running ratesetting agencies, or planning agencies, or even hospital medicare/medicaid reimbursement agencies. That is the basic kind of policy decision where the bureaucrats need leadership from our elected representatives. And I would suggest the kind of direction needed is a directional policy like "Let's try to keep expenditures in health, say, increasing only 1 percent more than personal income," or not increasing any faster than personal income. I don't know what the decision should be, but Congress should give some kind of direction guide to planners, HCFA, et cetera.

As regards assessment of medical technology, I think that we're getting somewhere. It is rather interesting that I can't spend a dollar out of my pocket on a drug unless someone has said that it is better than what was already there, but I can spend $300 out of my insurer's pocket on some peice of technology that no one has proved is contributing very much of anything as far as increasing health status is concerned. That bothers me, but I think that at least we are moving in the right direction.

Now, let me give you a disturbing example. I don't know if you are aquainted with the Eastern Shore of Maryland; it's the other side of the Chesapeake Bay. It's rather remote though not totally isolated. There was a hospital over there that applied to their planning agency for a full-body scanner. They projected that they would have about 1,170 patients being brain-scanned, and about 630 patients being body-scanned.

Mr. SCHEUER. In a year?

Dr. COHEN. In a year.

The difference between buying a brain scanner and a body scanner is that it costs about an extra almost $500,000 to go to the latest full-body scanner—which they got permission to buy no less—than buying a relatively inexpensive brain scanner.

To treat those 630 patients with the body scan—which we are not even sure does very much for many of them—is going to cost an awful lot of money, but the decision was made to buy it.

I'm just not sure that is an appropriate decision—in fact, you could drive them up to Baltimore much cheaper.

Mr. SCHEUER. Are they well people, or are they severely injured people?

Dr. COHEN. The severely injured people, it's cheaper to bring them up by helicopter. I mean, we're only talking 630 people a year, and most of them are scheduled outpatient activities.

Mr. SCHEUER. They're outpatients, ambulatory?

Dr. COHEN. A lot of scanning is on outpatients.

Mr. SCHEUER. So then it would be no problem at all?

Dr. COHEN. It would be an inconvenience, but it certainly is an inconvenience that doesn't compare favorably with the inconvenience to the taxpayer's pocketbook of $500,000 and interest.

Mr. SCHEUER. You said a few moments ago about the hospitals' budgets—you don't care how they spend it. Do you think we ought to provide some incentives and disincentives within the economics of a hospital to get them to shift treatment of patients from tertiary hospital beds to outpatient, ambulatory care? That would reduce their budgets.

Can we force them to recast their system to be more cost-effective by how we give them their budget? I mean, do we have to say, we don't care how you spend this money?

Dr. COHEN. Well, I think the question has to do with how you determine what their revenues should be. And having determined what their revenues should be, how much responsibility you give them to decide how they are going to live within that constraint.

My feeling is that we should give them broad-based parameters for performance while saying "this is what your revenue constraint is," much like a competitive market faces a price—and each individual company can produce however well it pleases, but it has that constraint. We should tell the hospitals that this is how much we're going to pay for treating your case-mix of patients, and adjust that if your case-mix changes.

I think you should recognize they should not have an incentive to emphasize tonsillectomies because that would, you know, make it cheaper per case.

So it should be on a case-mix adjusted number of admissions. But having given them a revenue constraint, then you let them decide how many workers they are going to replace with machines, whether they are going to use all R.N.'s, or whether they are going to use R.N.'s and nurses aids and L.P.N.'s; that, I think, only they can decide.

I don't think anyone can run any particular hospital better than the board of the hospital should be able to.

Mr. SCHEUER. But we should provide them with some incentives, some kind of profit-sharing incentives that if they make savings that don't impact on the quality of health care——

Dr. COHEN. Exactly right. To the extent that they beat their budget they should be able to keep that money and continue keeping it.

I might indicate that I—my background, as you no doubt gathered, I am an economist. I studied under Fred Kahn at Cornell. He was my major professor. He is now the Chairman of the CAB. We have similar ideas I think as to reliance on the market, that regulatory intrusion should be held to a minimum, to give the industry performance parameters, constraints that it has to meet and then you let them run their own business.

Let me give you an example of how we differ quite considerably from one aspect of the administration bill, and that has to do with wage costs.

In October of 1976 we sent out a memorandum to the hospitals saying, in effect, "We dont't care what you wage policy is, but your revenue will be approved to go up no more than the cost of living."

So if the hospital's wage bill was, say, $20 million, and the cost of living in Baltimore that year was up 5.3 percent, we say, "OK, now, we will approve revenue to cover—not $20 million— but $20 million plus 5.3 percent."

Now, that does not mean that's what they should give in wages. They can give whatever they want in wages, but that is the revenue constraint; that's all they can charge the public. If they can generate more efficiencies by having fewer workers and replacing them with equipment, or having fewer workers, period, they make money.

Mr. SCHEUER. Or changing the mix of workers and having fewer high-priced technologists, and more nursing-extenders and doctor-extenders.

Dr. COHEN. Yes.

Actually, I happen to think you may be able to replace, perhaps, six nurses aides with four nurses, and it may be cost effective. It depends on the particular hospital. But as I say, that's their business. I don't know, for each individual hospital, when you should move up and when you should move down, but you have to give them the incentive to do it. That is to say, if they can save money doing that, they keep the money that they save.

And the hospitals responded very well to that system. In fact, what happened in that year and is continuing—that was the year that national hospital costs went up almost 16 percent, whereas in Maryland they went up a little less than 10 percent; but hospital revenue went up a little more than 10 percent; that is, hospital revenue went up 10.2 percent; hospital costs went up 9.7 percent. So the hospitals' profit margin increased, and that's fine. Everyone benefited.

Mr. SCHEUER. That was their walking-around money for things that they wanted to do that might have been innovative and creative and not reimbursable, and the taxpayers saved, too?

Mr. BEILENSON. I want to say, once a person is in the hospital, you have a problem—I mean it's going to be an expensive proposition.

As the doctor pointed out in his printed statement, the solutions to the proper incentives in the medical marketplace do not at all center around the hospital but among other things, could involve the physicians' decision as to whether or not to admit people to hospitals in the first place. Because once they are there, it's a high-cost problem no matter how hard you try to keep the cost down.

Dr. COHEN. I think that we have to recognize at the beginning that the preamble to medicare which I paraphrase as saying, "We're going to spend $300 billion in this industry, but we're not going to affect the way the industry operates," has to be recognized as incorrect.

If we don't change the way physicians evaluate the appropriateness and efficacy of the way they practice medicine, we are going to have no impact on hospital cost containment at all.

Mr. SCHEUER. We will suspend for about 10 minutes.

If you could wait, Dr. Cohen, I have a couple of questions to ask you. I want to ask you about caps on the hospitals, caps on a region; and I want to ask you about whether you think it might be feasible to have caps on a region, but with some congressional

decisionmaking on reducing the amount of money we spend on hospital care from medicare's present 42 percent, and recasting some of that into much less sophisticated, neighborhood-oriented—not sickness care, but preventive health care?

In other words, having dollar caps; but saying within these caps we're going to require you to move toward a preventive health system and way from the high technology tertiary hospital bed-oriented sickness care.

Dr. COHEN. All right.

Mr. SCHEUER. We will have a recess now.

[Whereupon, at 11:45 a.m., a short recess was taken.]

Mr. SCHEUER. OK, Dr. Cohen, in the last remaining minutes here, I am going to ask you take us by the hand up to the mountaintop—and see how we can build into the system some of these incentives and disincentives you're discussing.

Now, you discussed some disincentives for certain aspects of behavior, smoking and alcohol, via taxes.

What about involvement in violent situations which Dr. Fuchs elaborated was a major cost of health care—our proclivity to involve ourselves in violent situations either through the automobile or stabbing and so forth? I remember a table he had in that book showing the incidents of violent deaths among various groups in the population, and it was horrifying that in New York, among minority youths, the first cause of death between 18 and 25 was homicide. I don't think any other society on Earth has that kind of a figure.

How do we build in incentives and disincentives on diet—well, you have given us one—some kind of an annual health exam where if you're less than 20 pounds overweight their reimbursement would go to 90 percent rather than 80 percent, something like that. That would include diet and exercise, I suppose.

Now, violence, how would you discourage people from getting into violent situations that are extraordinary expensive? Would you say that if they cost society over $5,000 that they are going to have an extra layer on their income tax from now on to reimburse society over 10 years? How would you discourage that in a way that would have some meaning?

Go with that one and then I am going to ask you the question about capping.

Dr. COHEN. The one thing that I had suggested had to do with one particular form, and that is speeding on the highways.

I think we have a highway system which is designed for 70 miles an hour, with speed limits which are 55 miles an hour. And the question that I suppose, to a large extent, one might ask is, "To what extent is it really dangerous to speed on those highways, if speeding is going 65, as opposed to simply using up excess gasoline"? So I guess one of the questions is whether it is really dangerous or not.

However, if we did come to the conclusion that it does increase the possibilities of needing the health-delivery system then it seems to me that when someone is found guilty of speeding, then in addition to paying some fine for simply breaking the law or for some other particular reason, it might very well make sense to have them give a contribution to the health—you know, be fined

more—which, in effect, is a contribution to the health fund, associated with the increased probability that the health resources will be needed.

That, at least, is one possibility. But I think it would have to be considered with regard to others—I mean any moving violation which is unsafe—because it is likely to land people in a trauma center, might very well help contribute toward the financing of those trauma centers.

Victor Fuchs also points out the difference in the homicide rates in different places.

And I don't think anyone—I don't know how to solve problems of that sort other than pointing out that it may very well be that the contributions to health, as I suggested earlier, might be much more significant than from things other than what we think of as the health-delivery system. That is, if we thought for a moment of the World Health Organization-type definition of the health-delivery system, it is much broader than what the Comprehensive Health Planning Act thinks is a health-delivery system.

While we may almost be without limit on the money we pay on institutional health delivery, we severely limit the amount of money we spend on housing and things of that sort.

Mr. SCHEUER. Or on eyeglasses or on other perfectly clearly health-related services.

Dr. COHEN. That's right.

Yet it may very well be that those things would improve our health and reduce our proclivity for violence much more than having a new hospital or an emergency room on every corner.

One thing I would like to make clear is that when you are concentrating on the cost of technology and capital with regard to hospital costs, that is really a rather small part of what hospital costs are. Hospital costs, much like Government, are very labor intensive. And even for something like a CAT scanner, well over 50 percent of the cost over its life is the cost of staffing that CAT scanner and the supplies associated with it. You cannot look at the technology alone any more than you can look at buildings alone.

You may have seen an "NBC White Paper" several months ago where they suggested that the way to cut costs in Denver, Colo. was to board up 1,500 excess hospital beds and buy less CAT scanners. I would suggest that boarding up 1,500 beds does not save you anything unless you fired the 4,000 people staffing the 1,500 beds. And if the beds are already unstaffed, then boarding them up doesn't save much of anything anyway.

We really do have to recognize that hospital care is very labor intense, and that saving money is very difficult without threatening certain people's livelihood. I think one of the major things that Congress could do to make it easier to cut hospital costs in that area is to generally improve the employment situation so that you could not continually be told, "Well, if you throw them out of work then they are just going to go on welfare, so it's a cost to society one way or the other".

I think what we have to do is have a system whereby we didn't think of hospitals as an employer of last resort, but that we had a system which generated useful employment that was needed, so

that people who are not needed in hospitals to provide quality care could find work elsewhere. I think that is one of the problems.

Mr. SCHEUER. It seems to me there should be employment opportunities in the health-care system that redirected resources to a preventive-health model in terms of health counseling in neighborhoods; all kinds of paraprofessional outreach on diet, exercise, tobacco, alcohol, drugs, violence; counseling, especially in low-income neighborhoods.

It seems to me that some of the people, some of the low-income, especially minority, employees in large tertiary hospitals who are doing fairly routine work might find that they are capable of doing far more creative work and far more satisfying work in a neighborhood-based preventive health system where they might be doing counseling and they might be doing outreach work of various kinds than simply sorting laundry or serving meals off these big carts they shove down the corridors.

Dr. COHEN. I understand that health maintenance organizations do hire many more of those kinds of people than, for example, a hospital.

Mr. SCHEUER. Let's get to the question of capping by region. There has been some discussion of that.

What would you think of putting a cap on health-care cost of all kinds either by States or by regions, and then leaving it to the local decisionmakers to sort out how and to whom and for what?

Dr. COHEN. Well, it might be an improvement, but I would like to suggest that the theme of much of what I have been saying is that health care is one of many social needs. And what I would really like the local communities to recognize is that the amount of moneys spent on health has an opportunity cost in that there is less money to be spent on housing, education, highways, sanitation, et cetera, unless you define some of those as being within your definition of health.

So it really makes much more sense to include an amount of money which is the maximum, say, they would spend on health, but not require them to spend it on health; that is, they get that anyway, and if they wish to spend it some other way they can spend it some other way. Let them decide their local priorities.

If we can save money by keeping down the cost of health in our community, or simply decide we're going to keep down the cost of health by not having more than one CAT scanner when maybe four could be explained by medical reasons, we could decide instead we're going to have classsrooms of 18 instead of classrooms of 20. We just make that priority decision.

Then it would make more sense if we did something more on the block-grant order where they did recognize that all sorts of social services were competing for those funds——

Mr. SCHEUER. Dr. Cohen, I think you could easily make the case from the opportunity costs you have indicated here on page 13 of your testimony—whatever the cap was that you gave for health, if they wanted to save on high-technology, nonprimary care-related health costs, and direct them into additional primary care, and such things as housing for the elderly, the 4 million elderly on diets below the acceptable standards of nutrition; the 18 million who need eyeglasses; the 3 million people who need hearing aids;

the 16 million who need basic dental care—I think you could probably use up whatever of those savings in nonprimary care, high-technology health costs a particular region wanted to make.

You could easily invest them in an alternative but clearly health-related expenditure.

Dr. COHEN. You certainly can.

The question is whether the communities should be told that the money they save in acute care facilities has to be used for other kinds of health care as opposed to using it for other things, such as improving the educational system in that community, or the housing system in that community.

Mr. SCHEUER. What you're suggesting is, give it to them as walking-around money; give it to them as sheer profit that that community can spend in any way they want across the whole spectrum of public service?

Dr. COHEN. I think you will probably need some minimum standards of care, certainly for beneficiaries under medicaid/medicare. We can't say, "We're going to give you this money and if you vote not to have a medicare program you still get the money."

I think the Federal Government's job is to say, "These are the performance parameters we expect you to meet," just like it's our job to tell the hospital, "These are the performance parameters we expect you to meet, and if you beat them, you can use that excess however you want, you don't necessarily have to use them in the health-delivery system."

At least that's what I would suggest.

I think it is not improper to observe that when a community ages and shrinks, it finds it much easier to close classrooms than it does to close pediatric services. And I think a large reason for that is because pediatric service is not funded locally. The local people don't recognize an increase in their property tax or a potential decrease in their property tax because the money comes in from insurance sources. Whereas, when they cut back on ther classrooms they save money, and it's money they can use for other things, or simply for the advantage to their taxpayers of having a lower tax rate.

I think we have to put some more fiduciary interest in the decisionmakers for the decisions they make in the local health scene.

Mr. SCHEUER. Would you let local decisionmakers get into these very sensitive area questions of triage? Would you let them say, "Well, we are going to reduce the amount of money that we're spending on kidney dialysis for people in their eighties, and we're going to have more eyeglasses, more hearing aids, better nutrition, improved health for a far higher number of people?

Where would this kind of ethical and moral value judgments take place?

Dr. COHEN. Well, if the Federal Government determines—that is, if the Congress determines that it is social policy to fund all the costs of chronic renal failure of people, of whatever age, then I think that fund would have to be looked at as a separate income, a separate flow, and they would have to provide the services that you tell them has to be provided.

If, on the other hand, you determine there are other services which are, in effect, optional, and the level at which those services are provided are optional, then those are funds that they would have much more discretion to work with.

I certainly don't believe that I can determine whether everyone who has chronic renal failure should be cared for, but that is an appropriate decision of Congress.

Mr. SCHEUER. Well, who is going to make that determination?

Dr. COHEN. Well, either the decision can be made straight on, as we have under the medicare bill, or the decision can be made—individual communities can make that decision, and it would not be separately funded, it would be competing with everything else.

And it is not an easy decision to make at all. I don't know how to go about making such a decision. I have been consultant to the Federal Government in some of the studies it does on the ethical and moral implications of health research, and I have never felt anything has been answered. I just cannot answer those questions.

Mr. SCHEUER. Dr. Murray, do you have any questions?

Dr. MURRAY. I have one comment, Mr. Chairman. You might call it a take-home lesson. It is an assignment for all of our students.

You are on a subject that has great challenge. The principle on which some recommendations have been based is that it's the publicly elected representative who should make the value judgments, and the bureaucrats should do the technology, staffing, and so forth.

You referred in your testimony a few minutes ago to—quite a few minutes ago as a matter of fact—to the preference that bureaucrats should not make some of those hard decisions.

I certainly agree with you in the ideal or principle, but I have to note that it is very difficult for elected officials to make some of what you call the tough decisions. They can make them in one direction, which is give everybody everything. That is politically acceptable in the sense that no one is going to criticize so severely that he won't vote for you; but if you make the tough decisions in the other direction so that some will die because of neglect to provide the latest, the greatest and the most—that's very difficult, and politically rather impractical and perceived as insensitive.

Now, if elected people are to make those decisions, yet the way we bring them to office and keep them in office doesn't reward them for making clean, conscientious decisions, then what sort of balance might we make between interest of the elected office holder and the capabilities of the bureaucratic professional? They at least have their fingertips on sources of information that could give the values and numbers and relative merits and so on needed for weighing decisions. What sort of balance between those two positions can you devise which would make the decision process practical as well as reasonably close to the ideal?

Dr. COHEN. Let me give you an example. We set rates for hospitals services, and we try to set rates so that hospital patients pay the cost of their own care. In many cases we have had hospital boards and trustees saying that while they recognize that the cost of having a child in a hospital is $1,000, say, they would like us to set a rate of only $800, and set a rate in other service centers above

their costs, because the people who are having babies cannot afford $1,000.

And we have taken the position that that is a very clearcut tax and subsidy decision, and tax and subsidy decisions are to be made by the legislature—in our case, the legislature of the State of Maryland—that if they want people having babies to be subsidized by paying less than their care, they should tax everyone and give them the $200; it should not be us as bureaucrats to say, "OK, medical-surgical patients, we're going to charge you more than the cost of your care—tax you, in effect, so that we can then have a service sold to someone else at less than their cost."

Mr. SCHEUER. As a matter of fact, what legislature should be doing is thinking in far broader terms than that. They should be thinking in the terms of the $75,000 or $100,000 it costs to raise a child from birth to 18.

And if you want that much to have a pronatal policy in our country, then we ought to give each family that has a child, or each couple that has a child within or without the benefits of matrimony, a fund of $100,000 to spend on that child between birth and 18 so that that child would have proper schooling, proper summer camps, proper clothing, proper piano lessons, proper dental supervision—because we're talking about a considerable amount of money. I don't think it makes much sense just to pay the $200 to subsidize that child's hospital stay and for the mother's few days of postnatal recovery.

The proper thing is to go the whole way. If you really want a pronatal policy, pay the $100,000. At least that will help concentrate people's attention on what the problem really is. It "ain't" the 200 bucks.

Dr. COHEN. That's correct.

Mr. SCHEUER. I happen to be chairman of another committee in this Congress, the Select Committee on Population, and we think that our country ought to be thinking about many elements of pronatalism and what our policies really are or ought to be.

We wonder whether the country and Congress has really got its act together in its thinking about that problem from a holistic point of view. I suspect that we have not.

Well, Dr. Cohen, we cannot thank you enough for your very stimulating testimony. You are sort of a reincarnated ghost of Victor Fuchs, and we have enjoyed having both of you here this morning.

Dr. COHEN. Thank you.

Mr. SCHEUER. We will ask Louise Russell to come forward now.

Dr. Russell is a senior fellow in the economics studies program at the Brookings Institute.

We are delighted to have her with us here today.

We have approximately half an hour, Dr. Russell, before we're going to hear from Lester Breslow, because we are saving Dr. Breslow for Congressman Beilenson who is due to be back here at 1 o'clock.

So why don't we ask you just to chat with us informally for 12 or 15 minutes. You can hit the highlights of your own testimony. You can refer to anything that you have heard here this morning, or to anything that was said yesterday, then I am sure we will have

some questions for you. And we thank you very much for your patience in terms of this recasting.

I particularly would like to have you have a look at what you have heard from Dr. Cohen, and react to his testimony.

[The prepared statement of Dr. Louise Russell, Ph. D., senior fellow, economic studies program, the Brookings Institution is as follows:]

TECHNOLOGY AND THE COST OF MEDICAL CARE*

Louise B. Russell
Senior Fellow
The Brookings Institution

Statement prepared for the
Hearings on Technology and the Cost of Health Care
Subcommittee on Domestic and International
Scientific Planning, Analysis, and Cooperation
Committee on Science and Technology, House of Representatives

September 26, 1978

Thank you for the opportunity to testify this morning on the relationship between technology and medical care costs.

In our society, we believe that no one should go without medical care because he cannot afford it, that if there is some treatment that can save his life, or preserve or restore his health, that treatment should be provided. We have institutionalized this philosophy in the form of third party payment -- principally, private health insurance, Medicare and Medicaid. Third party payment is quite extensive for hospital care, which is for the majority of people the most expensive type of care and the type for which they are most often financially

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*The research on which this testimony is based was financed in part by the National Science Foundation under grants RDA 75-14274 and PRA 76-10470. The opinions expressed are my own and should not be attributed to the trustees, officers, or other staff members of The Brookings Institution, or the National Science Foundation.

unprepared. Currently, about 90 percent of all hospital costs are paid through third party payers.

The incentives set up by such extensive third party payment are a faithful reflection of our philosophy. Most patients pay little or nothing directly for hospital care, and the effect of the costs of their own care on the insurance premiums and taxes they pay is imperceptible. Thus, they and their doctors do not have to ask themselves, "Are the expected benefits worthwhile in view of the costs?" They have only to ask, "Is there a reasonable chance of some benefit?" -- no matter how small or how costly. This is not a distortion of the original philosophy. But the consequences of that philosophy are only now beginning to be fully appreciated.

For all practical purposes, there is an infinite number of good things that can be done in medical care. Some of them are very expensive. In some cases the benefits are very small, either in the sense that they are small for each person (relief from a cold) or that they only work for a small number of the people for whom they are tried (emergency surgery that saves one person and fails for the other 99). As we are discovering, it is enormously expensive to try to provide everything that might be of some benefit. This is the crux of the cost problem.

I will draw on my own research on hospital technologies to provide some specific examples that illustrate what the "cost problem" is about, and the sorts of decisions we face if we want to deal with it. I will describe two examples -- intensive care and renal dialysis.[1/]

[1/] The material in the next two sections is from Louise B. Russell, Technology in Hospitals: Medical Advances and Their Diffusion, May 1978, a report prepared for the National Science Foundation under grant no. PRA76-10470.

Intensive Care

Intensive care has changed the character of hospitals and hospital care in the last 25 years. It is based on the simple idea that critically ill patients need close observation, constant nursing care, and quick action in a crisis, and that the most efficient way to provide this care is to bring these patients together in one place with the most sophisticated equipment and highly trained people in the hospital. Its earliest form was the postoperative recovery room, followed in turn by the mixed intensive care unit -- which accepts people with virtually any critical condition, and separate units for coronary patients. Large hospitals have more specialized units and sub-units -- separate units for medical and surgical patients, stroke units, respiratory units, renal units, burn units, neonatal units for the intensive care of newborns, pediatric units, and no doubt others as well.

Today, virtually all hospitals with more than 100 beds have at least one kind of intensive care unit , as do the majority of smaller hospitals. And intensive care is still growing: between 1972 and 1976, the number of beds in mixed intensive and coronary care units in non-federal short term hospitals grew more than 30 percent. In 1976, they accounted for just over 5 percent of the beds in these hospitals.[2/]

Intensive care uses many more resources than does ordinary hospital care: more space; more, and more sophisticated, equipment --

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2/ Hospital Statistics, 1977 Edition, Chicago: American Hospital Association, 1977; also the 1973 edition.

for monitoring and life support; more laboratory tests; and more labor, especially nursing time. A recent survey by the American Hospital Association reports that, in hospitals of 100 or more beds, nursing time averaged 16 to 17 hours per patient day in intensive care, as against a little less than 6 hours on the wards.[3] This use of resources has been a major contributor to hospital costs. The available cost studies indicate that a day of intensive care costs at least three times as much as a day of ward care. Even this conservative ratio implies that intensive care accounts for at least 15 percent of total hospital costs.

What are we getting for the money? A brief review of studies of several of the many conditions that receive intensive care can indicate the general dimensions of the answer.

Stroke, for example, is one of the major causes of death in the United States, and some hospitals have created special intensive care units for its treatment. One study followed six hospitals for a period before and after the introduction of stroke units in three of them.[4] This design made it possible to observe the differences that existed between the two groups of hospitals before any of them had stroke units, and the changes that occurred in them over time, and thus gave the investigators more confidence that any results they might attribute to the stroke units were actually due to the units, and not to more general differences between

[3] William A. Michela, "Administrative Profiles: Employee Fringe Benefits," Hospitals, J.A.H.A., vol. 50 (November 1, 1976), p. 68.

[4] William E. Drake, Jr., Marsha J. Hamilton, Monica Carlsson and Jack Blumenkrantz, "Acute Stroke Management and Patient Outcome: The Value of Neurovascular Care Units (NCU)," Stroke, vol. 4 (November-December, 1973), pp. 933-945.

the two groups of hospitals. After correcting for the condition of the patients at the time they were brought to the hospital, the authors concluded that the mortality rate was the same in the hospitals with units as in those without. They did find two more modest advantages: patients admitted to the hospitals with stroke units developed fewer complications; and more of them improved over the course of their hospital stay in their ability to care for themselves.

Several studies of intensive care have been carried out by Griner and his colleagues in Rochester, New York. Griner[5/] examined the experience of patients with acute pulmonary edema (accumulation of fluid in the lungs) in the year before and the year after the opening of an intensive care unit in the study hospital; he could find no difference in mortality between the two years, although the more seriously ill patients were admitted to the ICU in the later year. Piper and Griner[6/] investigated the effect of intensive care on people who had tried to commit suicide by taking an overdose of drugs. Here too they found no difference in mortality rates. They did find that patients who received intensive care had fewer complications, but the difference was not large enough to be statistically significant.

A great many studies, of varying quality, have been done of intensive

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5/ Paul F. Griner, "Treatment of Acute Pulmonary Edema: Conventional or Intensive Care?", Annals of Internal Medicine, vol. 77 (October, 1972), pp. 501-506.

6/ Kenneth W. Piper and Paul F. Griner, "Suicide Attempts with Drug Overdose: Outcomes of Intensive vs. Conventional Floor Care," Archives of Internal Medicine, vol. 134 (October, 1974), pp. 703-706.

care for heart attacks (technically, myocardial infarction). Some of them do show a reduction in the mortality rate with intensive care, but at least an equal number do not.[7/] One very carefully designed British study -- it may be the only study of myocardial infarction that has ever assigned patients randomly to different types of care -- examined an alternative that is seldom considered in this country, home care. The study found that, overall, there was no difference in mortality between heart attack patients given intensive care and those treated at home.[8/]

Each of these studies can be criticized on various grounds. In particular, many of them look only at mortality rates and do not consider other possible outcomes, such as less disability among those who survive. But these studies point to the conclusion that the benefits of intensive care are, in the aggregate, fairly small. It is not like penicillin, a therapy with results so consistent and impressive that no controlled trial was needed.[9/] The benefits of intensive care are of a lower

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7/ See, for example, the review and study in K. Astvad and others, "Mortality from Acute Myocardial Infarction Before and After Establishment of a Coronary Care Unit," British Medical Journal, vol. 1 (March 23, 1974), pp. 567-69.

8/ H. G. Mather and others, "Myocardial Infarction: A Comparison Between Home and Hospital Care for Patients," British Medical Journal, vol. 1 (April 17, 1976), pp. 925-929. When the results were examined in more detail, they showed that one group of patients -- those over 60 who did not have low blood pressure immediately following the attack -- actually did significantly better at home.

9/ A. L. Cochrane, Effectiveness and [illegible]cy: Random Reflections on Health Services, (England: The Nu[illegible]rincial Hospitals Trust, 1972).

order of magnitude -- a reduction in complications for certain groups of patients, perhaps reduced mortality for others. Its costs are of the first order of magnitude.

Renal Dialysis

The use of dialysis for patients with chronic kidney failure was made possible by a series of inventions and experiments in the late 1950s and early 1960s. The first programs of long term dialysis were set up in the early 1960s, supported in large part by federal money for medical research, and a little later, federal money for the demonstration of new medical techniques. By 1967 about 1000 people were on long term dialysis, but it was estimated that another 6000 died each year because there was not enough money to treat them.[9/] These numbers represent approximately 35 new dialysis patients per million population each year.

As the number of patients on dialysis continued to grow during the later 1960s and the early 1970s, the pressure mounted for the federal government to relieve patients and other payers of the expense of this treatment and to make it more widely available. On July 1, 1973, the Medicare program began to help pay the costs of dialysis, and kidney transplants, for virtually anyone who needed them.

Today the most frequently quoted estimate of new patients is 60 per million per year, compared to the 35 per million of a decade

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9/ Herbert E. Klarman, John O'S. Francis, and Gerald D. Rosenthal, "Cost Effectiveness Analysis Applied tothe Treatment of Chronic Renal Disease," Medical Care, vol. VI (January-February, 1968), pp. 48-54.

ago.[10] The difference is due to the changes that have taken place in patient selection in response to the more liberal financing. In 1967, when the number of places in dialysis programs was much smaller than the number of people with kidney failure, the Committee on Chronic Kidney Disease recommended that dialysis be limited primarily to patients between 15 and 45 years of age, and that the patients selected should not have any irremediable disease other than their kidney disease; severe arteriosclerotic heart disease and hypertension were mentioned specifically.[11] Today, there is essentially only one criterion for acceptance into a dialysis program -- disabling uremia (uremia is an excess of metabolic wastes in the blood). Very young and very old patients are accepted, and a large proportion of dialysis patients suffer from serious diseases other than kidney failure -- cancer, diabetes, and liver disease among them.[12]

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[10] Serafino Garella, Joseph A. Chazan, and Sewell I. Kahn, "Treatment of End Stage Renal Disease in Rhode Island: A Status Report," Rhode Island Medical Journal, vol. 58 (April, 1975), pp. 151-155+; Dan B. McLaughlin and Fred L. Shapiro, "Regional Kidney Disease Network Offers Efficient Care, Operation," Hospitals, J.A.H.A., vol. 50 (January 1, 1976), pp. 89-92; Joseph S. Pliskin, Theodore I. Steinman, Edmund G. Lowrie, and Clyde H. Beck, Jr., "Hemodialysis -- Projecting Future Bed Needs: Deterministic and Probabilistic Forecasting," Computers and Biomedical Research, vol. 9 (August, 1976), pp. 317-336.

[11] Klarman and others, "Cost Effectiveness Analysis Applied to the Treatment of Chronic Renal Disease."

[12] Garella and others, "Treatment of End Stage Renal Disease in Rhode Island;" Roger Platt, "Planning for Dialysis and Transplantation Facilities," Medical Care, vol. XI (May-June, 1973), pp. 199-213.

Another shift, which started with the introduction of Medicare financing for dialysis, is the shift from dialysis at home to dialysis in outpatient centers. In 1972, just before Medicare started paying for dialysis, 40 percent of all dialysis patients dialyzed at home. In 1977, this proportion had dropped to less than 20 percent, although in Europe the proportion of home patients continued to rise over the same years.[13/] The decline has been cause for concern because dialysis in an outpatient center is so much more expensive than dialysis at home. One recent study estimated the costs of home dialysis in 1973 at $6729 per year, compared to $16,520 per year in a "limited care" outpatient center and $24,738 in a hospital outpatient center.[14/]

Renal dialysis is clearly of benefit to the patient. While it is not without risks, it unquestionably prolongs the lives of people who would be unable to survive without it. Quite naturally, as third party payment has increased, the procedure has been extended to people who gain less from it in terms of added years or months of life and of the quality of that life. And increasingly dialysis is being done in outpatient centers, which relieves the patient's family of heavy

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13/ Medicare End-Stage Renal Disease Program Amendments , Hearings before the Committee on Ways and Means, 95 Cong., 1 sess. (GPO, 1977).

14/ Paul A. Hoffstein, Keatha K. Kreuger, and Robert J. Wineman, "Dialysis Costs: Results of a Diverse Sample Study," Kidney International, vol. 9 (1976), pp. 286-293. These estimates exclude the costs of: radiology; physicians' services; the surgery necessary to create the permanent entryway into the patient's circulatory system; and the costs that result when home or center patients must be admitted to the hospital, because of problems associated with the dialysis or for treatment of the complications ofthe disease itself, or when home patients must return to a center.

responsibilities, but costs the taxpayer much more. One can accept that these are real benefits, without losing sight of the fact that they may be small relative to the cost.

Conclusion

The purpose of these hearings is to consider how the federal government might best influence the development, evaluation, and use of technologies. I think that more evaluation of the medical, social, and economic aspects of medical technologies could be useful -- to government officials, to physicians, and to consumers. In concluding, I would like to make two points about the usefulness of evaluation.

First, I think it is unlikely that, by doing more evaluations, we will uncover a great many technologies that are without benefit, and therefore "unnecessary." I think it is much more likely that we will find many cases in which the benefits of a technology are, for many potential users at least, rather small, quite costly, or both. The purpose of the evaluations should be to establish those benefits and costs as precisely as possible.

Second, if I am correct, the information provided by evaluations will not make the decisions for us. If there were many technologies that were truly without benefit, solving the cost problem would be relatively easy because it would consist of discarding things that everyone could agree were unnecessary. But as I have indicated, the problem is considerably more difficult. Many technologies do have some value. Better evaluations would still leave us with difficult decisions to make -- when is a benefit too small, when is it too costly, and how and where shall we draw the new lines?

TESTIMONY OF DR. LOUISE RUSSELL

Dr. RUSSELL. Thank you, Mr. Chairman. Then I will lead into the review of my testimony that way.

I found that I agreed with the second half of his testimony but not with the first half.

I certainly agree that we have a set of priorities in medical care that we do not apply to the rest of our economy: We think that anything that's of any benefit ought to be done in medical care. We don't apply the same criterion elsewhere. The question is: Do we want to change those priorities?

The first part of Dr. Cohen's testimony made it sound as though this were going to be easy to do, easy in the sense that nobody would have to give up anything they really wanted. He referred to fee-for-service payment of doctors, and inefficiencies in our hospitals, and things that are being done that are, quote, "unnecessary" unquote.

The thrust of my testimony this morning is that, in fact, I think the bulk of the cost problem comes from a much more difficult sort of phenomenon; which is, that we are doing a lot of things that have some benefit, but either they don't have very much benefit or they are extremely expensive.

If they had absolutely no benefit, the problem would be relatively easy to resolve. The few people that are profiting from them could be pushed aside. The rest of the world would agree that we could get rid of these things, and then we could stop paying for them.

The problem is that they do have some benefit. And we have this philosophy that, in medical care, somehow things are different. We feel that when we are faced with a situation which threatens our life or our health, we ought not to have to worry about whether this next thing—which might work, but it's sort of chancy and terribly expensive—should be done. We ought to be able to do it.

We have financed the medical care system in line with this philosophy, and we are discovering that it is very expensive to finance a system like that. So I think that if and when we finally decide we're committing more resources than we feel we can to medical care, we're going to be forced back to making decisions about when are benefits too small or too costly. And it's going to hurt because it's not a zero benefit, it really is benefiting somebody.

Mr. SCHEUER. You mean it may be benefiting the provider?

Dr. RUSSELL. No; I'm talking about the patient. I grant that there are cases of fraud, and cases of abuse and inefficiencies. But I think the central problem in cost is that there are things that are beneficial to the patient, but they are either very expensive or the benefits are very small.

Mr. SCHEUER. Or both.

Dr. RUSSELL. And there are just an infinite number of things like that. We can all think of cases in which people didn't get medical care that could have helped them out a bit. Although we are already providing an enormous amount of medical care, we can think of plenty of places where we could add on.

Mr. SCHEUER. In other words, what you're saying from the economist's point of view: When do you stop spending the extra marginal dollar when diminishing returns have long since set in. Isn't that what you're saying?

Dr. RUSSELL. Yes.

And we have a very strongly held philosophy, I think, that in medical care we shouldn't have to do without; that if there is any chance that something is going to help out—and it's our life and our health—we want to go ahead and try it.

Mr. SCHEUER. No matter what the marginal—what do you call that last dollar——

Dr. RUSSELL. The marginal benefit or marginal utility.

Mr. SCHEUER. Well, we hear this rhetoric all the time; that everybody in America is entitled to the very best. Well, "the very best" implies spending that dollar where the marginal utility or benefit is virtually at a vanishing point, and that comes after a lot of other dollars.

Can we afford that kind of a health system? Is it reasonable to talk about—is it fair and honest to talk about it when it probably is far beyond our capability to provide every American with the very best of health care; which means an awful lot of marginal dollars, virtually down to the vanishing point?

Dr. RUSSELL. I think it's going to require a change in the way we talk about the cost problem. Too much of the discussion that goes on tends to focus on the idea that there is a lot of fraud, and a lot of inefficient hospitals, and a lot of stuff being done that's unnecessary—with the implication that if the patient knew what was going on he wouldn't want it done to him.

I think that is very misleading. There is some of that. But in most cases, if the patient knew what was going on he would still want it done to him.

Mr. SCHEUER. He might want more.

Dr. RUSSELL. He might more more. And this leaves us with the problem that we're trying to convince people that the cost problem is easy to solve. But as soon as it gets to the local level they can see that they have to give up something they want, and this leads to the reaction: "Well, wait a minute—we didn't think this was what it meant. You can't cut the cost here." So I think we do need to change the way we talk about cost control.

It may be that when the question is put in the terms which I think are the correct way to put it, people are willing to go well beyond 9 percent of the GNP. They might not want to stop at that point. They might rather keep on trying and see how much further they can go before they get to the point—maybe 15 percent where they say: "This is beginning to hurt too much financially."

Mr. SCHEUER. Don't we have to crank into their consciousness the concept of opportunity costs, or some of what those alternative expenditures might produce in the way of improvements in their standard of living?

Dr. RUSSELL. Well, I think so. But I do think that first of all we have to change the way we talk about medical costs. We are putting it now in terms that costs will be easy to control because we're not going to have to give up anything we really want anyway.

Mr. SCHEUER. I really don't think that Dr. Cohen—I hate to put words in anybody's mouth—but I really sincerely doubt that it was his intention to purvey the claim that this is going to be easy to do.

Dr. RUSSELL. It was obviously not the intention of the second half of his talk, but I think the first half of his talk tended to fall in with that.

In my own testimony, I think the example that portrays most clearly the kinds of problems you run into is the kidney dialysis program. We started out with an idea that here is a fixed program. There are just so many people that need this kind of care. We'll give it to them and that will solve the problem.

When we started considering the problem there were 1,000 people on dialysis. Six thousand people were estimated to die every year because of lack of funds and equipment to take care of them. That turns out to be 35 new patients per million population per year.

Well, we thought "Really, that's ridiculous. We've got a lot of money in this country. Why don't we help these people out? It's a very expensive treatment. Well will give them this treatment."

So we passed the medicare program. Well we discovered it's not——

Mr. SCHEUER. How much per patient per year are we spending on this?

Dr. RUSSELL. At the end of fiscal 1977, the cost per patient per year under the dialysis program was running about $17,000 a year.

We have had the medicare program since 1973, and the current estimates are that there are 60 new patients per million per year who can benefit from dialysis, as opposed to 35. What happened is, that, as the financing got more liberal, we began to realize there were other people out there who could benefit from dialysis. When the financing was very tight, we were very strict in our criteria of who should benefit.

Ten years ago the criteria were to limit dialysis to people between 15 and 45 who did not have any other serious diseases. Now that financing is liberal, we realize there are a lot more people—people under 15 and over 45, people who have other serious diseases besides kidney disease—who will have their lives extended by being put on dialysis.

We changed the problem. We realized there was very much more we could be doing, and when we tried to do that, too, we got ourselves into endlessly escalating costs.

I think the shift to outpatient centers has some of the same elements in it. You can certainly argue that it is easier for the patient's family if he gets this care at an outpatient center because they don't have to be there to, help him and watch him while he's on dialysis. But it is a great deal more expensive for the taxpayer.

Mr. SCHEUER. Than home care?

Dr. RUSSELL. Than home care.

It's a real benefit, but the difference in expense to the taxpayer is considerable. I can give you some numbers but they are a little bit misleading in the sense that they leave out some things. They probably leave out a bit more for home care than they do for the center.

It cost, in 1973, about $7,000 to do dialysis at home. It cost between $15,000 and $25,000 to do it in the outpatient center, depending on the range of services and how closely associated the center was with a hospital.

Mr. SCHEUER. What about the concept that Dr. Cohen suggested, this is if we know it costs $7,000 for home care, why don't we provide them with $10,000? It's sort of a profit sharing thing to induce them to opt for home care. It's certainly a lot better than $15,000 or $20,000

Dr. RUSSELL. We certainly could do something like that.

That would be making an explicit decision that even if it's more beneficial for them and their families to do it in the outpatient center, we're not going to pay for that.

Mr. SCHEUER. Is it more life extending, or just a matter of convenience?

Dr. RUSSELL. My impression is that, medically, there's not much to be argued in favor of the center. It's more that it is convenient for the family. They can continue to go to work or to school instead of tending the sick relative.

Mr. SCHEUER. Let's say, well, if it's only a matter of convenience to the family and there are no life-extending differences, it seems to me that for another couple thousand dollars that family might very well undergo that inconvenience. If we threw in the extra $3,000 or $4,000 they could hire the visiting nurse or take it as income themselves if they wanted to perform that function.

Dr. RUSSELL. We could offer them that choice. I don't know how many of them would take it.

And there are a number of patients for whom it is argued—I don't know what the percentage is—that they have so many other problems besides the dialysis that they need something more structured than dialysis at home. If we want to make absolutely certain no dialysis patient is faced with a problem that he can't handle, then perhaps they should all be in centers. It is, again, a tradeoff between small benefits and high cost. But real benefits are involved, which makes it a very difficult decision.

Mr. SCHEUER. We thank you very, very much.

Dr. Wells?

Dr. WELLS. You did not discuss the intensive-care aspect of your testimony, Dr. Russell.

In regard to intensive-care units, above and beyond dialysis, would you care to touch on some of the highlights there?

Dr. RUSSELL. Surely.

I have been doing research on a number of hospital technologies.

Mr. SCHEUER. I take it you are an economist.

Dr. RUSSELL. Yes, I am.

Mr. SCHEUER. A health economist?

Dr. RUSSELL. Yes. Primarily medical economics.

I picked the intensive-care and renal dialysis examples because they are particularly good ones, but I worked on a number of others which showed the same general characteristics.

Intensive care is a good example because it has become such an extraordinarily large part of what we do in hospitals, and in spite of the fact that it has been spreading for the last 15, 20, or 25 years, it's still growing extremely fast.

On the cost side—to give you some idea of its size—the number of beds in intensive care grew more than 30 percent between 1972 and 1976, and they now count for a bit over 5 percent of all hospital beds.

They account for considerably more of our hospital costs. Intensive care accounts for at least 15 percent of what we spend on hospital care. There have been other estimates that suggest it may be as high as 30 percent, but I haven't really looked into them, so I can't speak with much authority about them.

Mr. SCHEUER. Still on a cost-benefit basis, those expenditures may be more life extending per dollar than many other hospital expenditures.

Dr. RUSSELL. It's possible.

I couldn't make the comparison between that and some other hospital expenditure. But the studies that have been done suggest the benefits of intensive care are fairly small.

Dr. WELLS. The reason I asked you to pursue this, having had a heart attack myself, I was struck by the study that showed, for patients recovering from a myocardial infarction, the mortality rate was not significantly different between home care and hospital care and intensive-care units.

Dr. RUSSELL. That was a British study where they compared heart attack patients, and to the extent that they could, they tried to assign patients randomly to home care and intensive care. Any patient that went to the hospital got some intensive care. They did not find any difference in the mortality rate between the patients who were cared for at home and the patients who were cared for in intensive care.

In fact, when they started breaking it down by more specific characteristics, there was one group that did better at home. Those were people over 60 who had low blood pressure right after the attack. If you had those characteristics, apparently you were better off going home than going to the intensive-care unit.

Mr. SCHEUER. And why would that be?

Dr. RUSSELL. That I couldn't tell you.

It has been suggested that going to the intensive-care unit scares people into having a heart attack, but I don't know if that is the explanation in this case.

There's an enormous number of conditions that are taken care of in intensive care. Heart attack is certainly one of the big ones. But there are a number of studies of other conditions which suggest the same sort of things: that if there are advantages they must be fairly small because they don't show up very clearly.

Mr. SCHEUER. That's being very charitable.

Dr. RUSSELL. You can't prove that there is absolutely no advantage.

Mr. SCHEUER. You're saying that statistics don't indicate any.

Dr. RUSSELL. In some cases they don't.

For example, you can find half a dozen studies that show the mortality rate for heart attacks was reduced in that hospital, or in that area, with the use of intensive care. And you can find an equal number of studies that couldn't find any difference.

So you have to ask, first of all: Were they all doing the same thing? Were they correcting for differences in patients?

But it suggests that intensive care is not a major factor. Its effect can be swamped by moderate variations in these other factors.

Mr. SCHEUER. You are giving us a classic example of the statement, "Figures don't lie but liars often figure." You can prove anything you want given a competent statistical background.

Dr. RUSSELL. If you assume that intensive care is a little beneficial but not greatly beneficial, then you would expect to find this kind of thing. A study in one unit might not find any effect. The next unit would do a study and would find one.

Mr. SCHEUER. But you would really think that that concentration of resources, high technology, the elite of our medical profession the elite of the specialists with that concentration of manpower and technology, some clearly definable good would flow from that.

Dr. RUSSELL. Not all of the possible effects were examined in the heart attack studies. In a study of stroke they looked not only at the mortality rate but the number of complications and the shape the patient was in when he left the hospital. They found the mortality rate was not any different between intensive care and ward care. But they found that the patients in intensive care had fewer complications and were better able to take care of themselves at the point they left the hospital.

It's a small benefit, but a real benefit.

Mr. SCHEUER. That's an identifiable payoff.

Dr. RUSSELL. So you can criticize the studies that look only at mortality rates. You could say there's a lot more to look at. They haven't told us everything.

But I think you could also argue that when you are spending 15 percent or more of hospital costs on this one thing, you sort of expect to get a big bang in results, and you are not getting it. You are getting small incremental advantages for some patients in some situations.

Dr. WELLS. That's what struck me about the argument or case you seem to have presented. Intensive-care units are really the embodiment of the high-technology investment. Yet, the payoff is certainly debatable.

Dr. RUSSELL. Yes.

It seems safe to say it is fairly small. And this is what will happen whenever you take off the economic constraints and say, "We don't want anyone to have to worry about what the costs are. If you think this is going to help, if there's a chance it is going to help, go to it." There is a chance that it's going to help, so they go to it.

And the question is: Do we want to say that chance is too small in view of the expense? I have talked to a number of doctors and potential patients, and a lot of them want those intensive-care units there.

Mr. SCHEUER. A lot of doctors want it?

Dr. RUSSELL. And patients, too.

In one panel discussion, I started to mention the British study and the moderator said, "Let me tell you, if my father-in-law or father fell to the ground with a heart attack and some doctor came up to me and said you could take care of this guy just as well at home, I would say to my wife, "the guy is out of his mind, let's go find another doctor."

So patients also have a sense that there is an extra measure of security, and they want that extra measure of security—as long as they do not have to pay the full cost of it.

Mr. SCHEUER. So long as they are not going to pay virtually any of it.

Dr. RUSSELL. Right.

With insurance they won't have to do that. And they like the philosophy behind insurance: That they should not have to worry about how much it's going to cost; that if there is a chance that intensive care is safer and it's going to give them an extra edge, however small, they would——

Mr. SCHEUER. You have a little potential conflict here; intrafamily conflict between the patient, who might want to be in the intensive-care unit in the hospital, and the family where, if we gave them some kind of a profit sharing cost assessing sharing, or a little incentive of $3,000 that we talked about before, if the family decided they wanted that $3,000 and they would take care of the old geezer at home, the patient may say "Hey, hold the phone."

Dr. RUSSELL. That is right.

Mr. SCHEUER. I could see the potential for some rather sensitive intrafamily situations, intrafamily conflict of considerable proportions.

Dr. RUSSELL. I think that's quite right. But I think the major point I want to get across is that this technology boom is not being pushed by just doctors and hospitals for their own interests. The patients are right in there with them and they are in favor of these small incremental steps toward better mortality.

Dr. WELLS. Dr. Russell, when I was being hauled off, I felt a lot better that I was going to an intensive-care unit than going home.

Mr. SCHEUER. How does society handle this? I mean you stated the problem brilliantly, you know, what kind of response does this committee have, or the Health Committee of the House on which I also serve—what should our response be?

Dr. RUSSELL. I have looked at several other countries trying to find out what they are doing. My impression is that except for Britain, where they have a tight budget constraint, most of the other countries keep trying to do everything—the way we are continuing to try to do everything. They have not yet reached the point where they are willing to say, "We're going to put some fairly severe brakes on the growth in this sector."

Mr. SCHEUER. Wait a minute, Dr. Russell. I didn't think there is any country in the world that spends more than 6 or 6½ percent of the GNP on health care.

Dr. RUSSELL. That's not true.

Mr. SCHEUER. That's not true?

Dr. RUSSELL. No. The statistics are old and they are very bad. But there are several that are in the 7, 8, or 9 percent range.

Mr. SCHEUER. I didn't know that.

Dr. RUSSELL. West Germany, France, Sweden, and Canada are the ones I have seen that definitely——

Mr. SCHEUER. You mean they have health delivery systems in those countries where anybody who has a severe heart attack probably gets carted off the what we would call an intensive-care

unit? Do they have them that pervasively throughout these countries?

Dr. Russell. Yes. I would be sure about Scandanavia. I have not looked at these countries in depth, but for the most part they are right up there with us, looking at the same technologies, and considering the same problems, and, for the most part, trying to finance them.

France, for example, passed in 1970, a law in which they are trying to set ratios of technologies to population: How many open-heart surgery units should we have? How many cobalt units? Et cetera.

One of the things that interested me—I can't make comparisons in all cases—but the ratio they set for cobalt is higher than the ratio of cobalt to population which we now have. They said there ought to be five cobalt units per million population. We don't have that many at the present time in the United States.

Mr. Scheuer. How about CAT scanners?

Dr. Russell. They have established a ratio of one scanner per million population. And there, if you include the ones we have on order, they would be somewhat below us.

Mr. Scheuer. Well, take New York City that has a population of 7¼ million people—I don't know how many CAT scanners they have, but it would have to be in the hundreds, wouldn't it, between private practitioners, and hospitals?

Dr. Russell. I would have to ask Dave Banta if he could answer that one.

[David Banta, Office of Technology Assessment, Congress; from the audience.] New York City has about 40.

Mr. Scheuer. Well, that's certainly not one per million.

Dr. Russell. Well, I used some of the OTA's old statistics to come up with this. I think the numbers are something like 1.5 per million in the United States, but I don't know if you have ever made that calculation to check me out [indicating to Dr. Banta].

Dr. Banta. CT scanners in the United States presently would be about 4.8 per million. France has 0.2 per million at the moment.

Dr. Russell. They are behind us on CT scanners and ahead of us on cobalt.

Mr. Scheuer. Then it pays you to think of what kind of a sickness you're going to get when you go to France.

Dr. Russell. But they all have various ways of trying to deal with this problem; and, for the most part, they have not said, as Britain does: "Here is the money we have got. If you can't do it all, we're sorry, but you can't."

Mr. Scheuer. And they say that to whom?

Dr. Russell. Well, the money goes to the Department of Health and Social Services. And I'm not sure that they say it to any one person, but they do have a waiting list of 500,000 people for their hospitals. And I am told that when the waiting lists start to get very long you don't even get an appointment with the consultant, which means that you don't get put on the waiting list. So at a certain point the waiting list stops being a good measure of how many people are waiting.

They also have considerably fewer people on dialysis than we do. There is considerable evidence that the price that they pay for

spending less of their GNP for medical care is that they are able to do less——

Mr. SCHEUER. They ration?

Dr. RUSSELL. They ration; yes.

Mr. SCHEUER. And they queue up.

Dr. RUSSELL. Yes.

If you have private insurance, which is available in Britain, you can go to a private hospital—do what they call "jump the queue." But most of them stay in the queue.

Mr. SCHEUER. They can't afford to "jump the queue."

Dr. RUSSELL. That's quite possible.

Mr. SCHEUER. Well, this is really a nest of political problems.

Dr. RUSSELL. I think the decision is a very difficult one to make. I wish that it were simpler—that they could just get rid of a lot of the stuff—but I don't think that's the way it is.

Dr. WELLS. What you suggest here then is we will probably keep going in this direction of 9, 10, 11, or 12 until some kind of consensus emerges that this is enough.

Dr. RUSSELL. That's what I would say.

I would say that we're only at the beginning of that now. Not enough people either recognize that's the choice, or, I think, are prepared to say that they wouldn't spend any more and would forgo the benefit. Instead I think a lot of people would be willing to spend some more and see how much further it goes before they really begin to feel the pinch.

Mr. SCHEUER. The question is: Would they be willing to spend more in vacuo, or would they be willing to spend more with a clear understanding of the trade-off they're making, of the opportunity cost they're paying, and the missed services for eyeglasses and the nutrition for the elderly, braces for the elderly, subsidized housing for the elderly, which are perfectly clearly health related?

I mean that's a distinction with a real difference. It's one thing for people to say, "Gimme, gimme, gimme," in vacuo, without any or else, or what, or how much.

It's another thing for people to clearly understand what the trade-offs are and what the opportunity costs are and then to make the decision we should go from 9 percent of GNP to 15 percent of GNP at a time when we're operating under the constraints of a proposition 13, and where we are operating with a finite limit on the amount of resources we're willing to devote to all of these public sector service programs.

Dr. RUSSELL. I agree.

And I think the faster the discussion can be recast in those terms—that we have to give up things in order to get this—the more quickly we will come to the point where we will say, "This is enough." But at the moment it's not being conducted in those terms. Everone is saying, "Well, let's go ahead with this," and the percentage keeps inching up.

Mr. SCHEUER. You have given us some extraordinarily illuminating insights, Dr. Russell. It is almost painful how deeply you have cut, you have gone right to the bone.

It's really a big question to me of whether our political system can make these kinds of decisions. I am not sure they can.

You know, we have seen an example of single group politics in this recent election. Don Frasier, one of our most terrific Congressmen went down the tubes out there in Minnesota. He had antagonized too many single group constituencies. He had antagonized the antiabortionists; he had antagonized the antigun control freaks; he had antagonized the snowmobile freaks, and the watermobile freaks; and I suppose he had antagonized the veterans group the way I have antagonized the veterans group. I voted for a fairer deal for the Vietnam vets and the Korean war vets who, compared to me when I came out of the service, needed more and got less. I went to Columbia Law School on the GI bill of rights—these vets are younger, they are blacker, they are poorer, they are less well educated, they are far more in need of a helping hand along the way, and we have given them but a small fraction of the benefits we gave ourselves, these much more nearly white, more middle class, fairly well educated, fairly affluent veterans of World War II.

You couldn't conceivably go through Columbia Law School with all tuition, all books, the way I did, today, if you were a Vietnam or Korean vet. So I voted for a better break for these younger vets, and I have caught unshirted hell for it.

And you talk about—why, I was at a meeting last weekend—and this is all very directly related to what we're talking about—I was invited to speak at a meeting of the Disabled American Veterans, the DAV, who were not affected at all by the change in veterans' preference, to Government jobs.

Because the change in veterans' preference, as I clearly explained to them, would only apply to those vets who were not disabled, who had no service-connected disability. So it doesn't affect any DAV's at all.

I thought it would quiet the whole group of them, but they were outraged because they took the position, you are eroding some benefits for some vets, and when you do that we know that we are next.

It's just like the argument of the gun control freaks—the antigun control freaks. They say, I know you are only talking registration, but confiscation will be next.

And you could say, look, we have been registering cars, that are lethal weapons, for a long time and we have never confiscated anyone's car. We simply want to know who has what. It's part of a regulatory mechanism. They don't believe it. Logic is out the window.

Now, when you start legislating about having a cap on kidney dialysis, you are not just impacting elderly people with kidney problems, you are impacting every person over the age of about 3, I would think, because we all are maybe going to be there some day. Who knows what my illness is going to be?

So—well, you are just getting into the most inflammatory and emotional, sensitive, and irrational area I can conceive of when you have start talking about playing triage with people who need kidney dialysis—I mean you could make a very narrowly defined group which, as you said, we can't take care of; but in terms of the anxiety, outrage, fear, terror that you would send out in wave after wave, I don't know which member of any publicly elected legisla-

tive body would want to face up to that kind of pressure much less make hard decisions.

Dr. Russell. I think it probably does get harder when you consider individual cases, like in dialysis.

In that sense, it may be easier to think in terms of caps on hospital budgets because nobody is quite sure who is going to lose.

Mr. Scheuer. But then the buck stops there. Who makes the decision in that hospital for the distribution of resources between kidney dialysis and more outpatient services, more outreach into the community, more preventive health services?

As long as they have got a cap that's a closed economic system. Somebody has got to make hard decisions there, and who is going to do it?

It might—well, I just don't know. But I suggest the doctors, the board of trustees, they are all human, they are all subject to peer group pressure. Their homes can be picketed. I mean it's a real horror story that we're into here, and I just don't know whether our system is capable of making rational decisions. I'm not sure that I have that wisdom or the will—in fact, I'm sure I don't.

Dr. Russell. I am an advocate of the introduction of coinsurance as one way of getting the patient and the doctor back into making decisions about the individual. And, as you probably know, coinsurance is about the least popular incentive that has ever been proposed for cost control. But I have become convinced the reason it is so unpopular is that it is the one solution that forces people to recognize what the cost problem is all about.

Dr. Wells. Did the British not reintroduce coinsurance into the national——

Dr. Russell. No, they have not. They have a few copayments on things like drugs and eyeglasses, but for hospital care and physician care, no.

Mr. Scheuer. You're talking about having 80-percent and 90-percent reimbursement, but having the patient pay some portion?

Dr. Russell. Yes.

Mr. Scheuer. What would you do with an elderly indigent person who couldn't afford—would you give him the kidney dialysis or wouldn't you?

Dr. Russell. My argument would be that you would adjust the percentage according to income. And you undoubtedly would have some people who would not be paying anything. But if the bulk of the people are paying something, that you would give you some control over the system.

It would not give you complete control over the system, even assuming you get them to agree to it. Every proposal for coinsurance comes with a proposal for a cap on the total amount that a patient would pay out over a year, so it doesn't completely bankrupt him. And there are a fair number of services that would inevitably take you above that cap, every single time. Dialysis would be one of them. Open heart surgery would be one. There are lots of these very expensive things.

Once you have done that you are back in the very same situation—nobody has to worry whether the next move is worth the resources.

So it's not by any means the complete solution. I would argue that it is a partial solution and would cut out a large segment of what we now have to worry about.

But, as I say, it's also a very unpopular solution due to those people who are not yet ready to say, "All right, there are some things that are so expensive that we are willing to give them up." And coinsurance makes you realize that that is what you are going to have to do.

I think that people hope that if we regulate we can have everything. I would argue that's false hope, but I think that is part of the reason coinsurance is more unpopular and regulation is more popular as a solution.

Mr. SCHEUER. Well, I suppose regulation could reduce some of the least cost effective forms of treatment where they are not involved in a life threatening situation, but when you come to the life extending treatments like kidney dialysis, I don't know. Obviously regulation cannot cope, and I don't know where that decision-making can be reasonably expected to take place.

Dr. RUSSELL. I'm not sure that anybody is prepared to have it take place yet.

Mr. SCHEUER. You have really stimulated us, Dr. Russell, and we are very grateful to you.

We may have some questions after we try and digest some of the moral and ethical and other challenges that you have given us, and we are grateful to you for your testimony. Thank you very much.

Dr. RUSSELL. Thank you.

Mr. SCHEUER. We have been waiting for Congressman Beilenson. He is going to try and get over here, but in the meantime we will ask Dr. Lester Breslow, UCLA, chairman of the Advisory Panel, OTA Study on Efficacy and Safety.

[The prepared statement of Dr. Lester Breslow, dean, School of Public Health, U.C.L.A.]

STATEMENT OF LESTER BRESLOW, M.D., M.P.H.[1]

Mr. Chairman and members of the Subcommittee: My name is Lester Breslow. I am pleased to respond to your invitation to discuss the important topic before you, Technology and the Cost of Health Care.

Now Dean of the UCLA School of Public Health, my work over the past 30 years has included health research and service as a consultant on health care matters to Federal and other agencies. Recently I served as chairman of the Advisory Panel for the OTA report, assessing the Efficacy and Safety of Medical Technologies.

Although a member of several health organizations, I want to emphasize that today I am appearing as an individual—not as a representative of the University of California, the OTA Advisory Panel mentioned above, or any other agency.

The OTA reports, Assessing the Efficacy and Safety of Medical Technologies, September 1978, and Policy Implications of the Computed Tomography (CT) Scanner, August 1978, constitute valuable resource documents for consideration of Technology and the Cost of Health Care. They indicate that the cost of using some old and some new medical technologies for which the extent of effectiveness is in serious doubt now must be measured in billions of dollars. The term effectiveness is used here in the sense of the OTA report, Assessing the Efficacy and Safety of Medical Technologies, namely, "the probability of benefit to individuals in a defined population from a medical technology for a given medical problem under average conditions of use." Just three long-used surgical procedures—hysterectomy, tonsillectomy and appendectomy—together entail expenditures of approximately $2 billion annually, in the face of considerable indication that a substantial proportion of

[1] Dean, School of Public Health, UCLA.

the operations may not be medically necessary. The accelerating introduction of new medical technologies is adding to such cost. For example, the use of the CT scanner, electronic fetal monitoring and coronary bypasss surgery already exceeds what can be scientifically justified and at a total cost, now or soon to be, greater than $2 billion annually. It should be noted that some use of every one of these technologies can be justified. For many cases of cancer of the uterus, hysterectopmy can be life-saving, and health benefit comes from certain applications of the other procedures mentioned. The problem lies more in the failure to assure appropriate use of technologies with some demonstrable benefit than in the use of those with no value.

How has this situation come about, and what can be done about it? In particular what should the role of the Federal government be?

To understand how the problem arises it may be helpful to examine the idealized version of the steps from medical research to community application formulated in the report, Assessing the Efficacy and Safety of Medical Technologies:

"The development, diffusion, and use of medical technologies is a process that has been described as including at least seven steps.[2]

1. Discovery, through research, of new knowledge, and relation of this knowledge to the existing knowledge base;
2. Translation of new knowledge, through applied research, into new technology, and development of a strategy for moving the technology into the health care system;
3. Evaluation of the safety and efficacy of new technology through such means as controlled clinical trials;
4. Development and operation of demonstration and control programs to demonstrate feasibility for widespread use;
5. Diffusion of the new technology, beginning with the trials and demonstrations and continuing through a process of increasing acceptance into medical practices;
6. Education of the professional and lay communities in use of the new technology; and
7. Skillful and balanced application of the new developments to the population.

Over the past few decades America, and the Congress in particular, have supported biomedical research leading to the discovery of new technologies. Also our nation has been paying generously for the technological services which comprise an ever-growing component of medical care. In fact our system of medical care, both the way it is organized and the way it is paid for, strongly encourages the application of such services. We have thus been supporting the first step-and-a-half of the process; and the seventh—application—we have been supporting to excess rather than in the "skillful and balanced" way described. We have relatively neglected the important second half of the second step as well as the third through the sixth steps. They have been largely abandoned to "market place" forces. The drive to technology resulting from research, coupled with the pull generated by our system of medical care toward application, whether justified or not, has led to the imbalance that now occasions your consideration of the topic and other expressions of concern about it.

Sometimes even when the critical step three has been undertaken, the forces at work smother a rational approach to the matter. For example, an excellent clinical trial of breast cancer detection, including routine mammography (X-ray) along with physician examinations, showed that such detection could reduce mortality from the disease by about 40 percent among women over 50 years of age. No value, however, was demonstrated for women under 50; and other evidence indicated some risk of actually inducing breast cancer through mammography, especially among younger women. Yet tremendous pressure was exerted to ride over the obvious evidence and to extend routine screening with mammography to younger women in the absence of demonstrated value, in the face of some risk, and with no commitment to ascertain whether new developments in the technology yielded any benefit that had not appeared in the original trial. Only after rather stormy controversy and national conferences was the National Cancer Institute sponsorship of application to women under 50 stopped. Control in the rest of the medical care system has been less complete and American women have been unfortunately confused about a technology that does have demonstrated value in some circumstances, but no demonstrated value in others. That experience illustrates the importance of "development of a strategy for moving the technology into the health care system," and steps three, four, five and six in so-called "technology transfer" in order to achieve number seven. We have too often neglected those steps, and rushed into excessive development and use of technology, at great expense.

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[2] Modified from U.S. Department of Health, Education, and Welfare, "Report of the President's Biomedical Research Panel." HEW Pub. No. OS 76-500, Washington, D.C.: Apr. 30. 1976.

We are now in the midst of two rather similar experiences, in the case of the CT scanner and in coronary bypass surgery. Both appear to offer some benefit but far smaller than would justify the proliferation of the technology. The CT scanner has value in diagnosing certain intracranial problems, but its value in other parts of the body has yet to be clearly demonstrated. Yet our nation has rushed into the purchase and increasing use of CT body scanners with expenditure rapidly escalating toward a billion dollars annually, and perhaps more.

Would it not be preferable for the Federal Government to ascertain the value of CT body scanning before launching widespread use of that technology when its efficacy is in serious doubt? Would that not be worth a substantial investment of time and money, especially when Federal tax dollars will ultimately be paying a large portion of the bill for CT body scanning?

What inhibits that approach and instead places at least 5 to 10 times as may CT scanners in operation as can be rationally justified now? I believe that the answer lies in our recent historic tendency to rely on medical technology for health, up to the point of not even paying serious attention to questions about its particular values; and our willingness to pay the bill no matter how much waste is involved.

I realize that "health planning" and "peer review" and other ventures have been initiated to deal with the problem of excessive use of medical technology whose efficacy has not been established. None of these ventures has yet been successful; meanwhile the problem is growing.

At some point the Federal Government should refuse to pay, directly or indirectly, for applications of medical technology when efficacy is in serious doubt. At the same time the Federal Government should commit itself to substantial support for developing an appropriate strategy and for steps three, four, five, and six in the progression from medical research to useful application. That would save money and benefit health.

Mr. SCHEUER. Now, my first question, Dr. Breslow, before you even start testifying is: Why was that study not called cost effectiveness, efficacy, and safety?

I mean, since reading Victor Fuch's book, I learned when people ask me about my wife, "How is she," I say, "Compared to whom?" Why are you not saying in that study, "Compared to what, at what opportunity cost, at what cost effectiveness."

Dr. BRESLOW. I understand, Mr. Scheuer, your concern with technology and the cost of health care. And I am prepared to discuss that topic. I think that there are implications—as a matter of fact, some statements in here [indicating to OTA report] that are highly pertinent to the cost issue.

Mr. SCHEUER. Your patting something over there. What are you patting?

Dr. BRESLOW. This is a report assessing the efficacy and safety of medical technologies by OTA, that has just come into my hands today. I think it's just been issued.

Mr. SCHEUER. Yes. Dr. Wells received it. We just got it yesterday.

Dr. BRESLOW. There is an issue of efficacy and safety which can be examined apart from the cost, certainly before we adopt a strategy.

In regard to the introduction of technologies, cost must be given appropriate consideration. And I would be pleased to work with the committee on that. But there is a separate issue of efficacy and safety that can be——

Mr. SCHEUER. Obviously we want to know whether it is safe or whether it works, because if it doesn't the whole question is moot.

Dr. BRESLOW. Surely

Mr. SCHEUER. But then you have only gotten into the ballpark when you answer those two questions.

Dr. BRESLOW. As a matter of fact, it is unfortunate that a great deal of the cost which we have incurred in health care has been

entered into without appropriate attention to efficacy and safety, and that is the issue that I would like to discuss with you today.

Mr. SCHEUER. Very good.

Dr. BRESLOW. The cost of using some old and some new medical technology for which the extent of effectiveness is in serious doubt now most be measured in billions of dollars.

But it isn't just a matter of cost, Mr. Scheuer. The first question is——

Mr. SCHEUER. Cost effectiveness, Dr. Breslow.

It's perfectly obvious when you talk about cost effectiveness, that you talk about what it produces on the one side and what it costs on the other side; and what it produces has to be a measure of safety and efficacy.

Nobody is saying you should not talk about safety and efficacy. That is the effects side of the cost effectiveness analysis. What I was talking about is how come there is not any cost input. And isn't that absolutely essential to the kind of decisionmaking we're talking about?

Dr. BRESLOW. I would like to discuss the cost implications with you. I do think it important to recognize, however, that one can examine the effectiveness of methods of doing, let's say, hysterectomies without any attention to their cost.

Mr. SCHEUER. I don't see that you can at all. Explain that to me. The British have a very much lower rate of hysterectomies than we.

Dr. BRESLOW. Correct.

Mr. SCHEUER. I had a long lecture on this by the head of the British Medical Association. He says there is not the least bit of evidence that the higher rate of hysterectomies in this country produces positive health outputs.

Dr. BRESLOW. I agree.

Mr. SCHEUER. OK. Then it's not worth any cost.

Dr. BRESLOW. I agree. That is precisely my point. One can examine three separable issues in regard to any medical technology: efficacy, safety, and the cost effectiveness of particular methods of using the technology.

Hysterectomy, tonsillectomy, and appendectomy together, in this country, entail expenditures of approximately $2 billion annually, in the face of considerable indication that a substantial proportion of the operations may not be medically necessary, just as you had mentioned.

The accelerating introduction of new medical technologies is adding to that kind of cost.

[Congressmen Beilenson returns.]

Mr. SCHEUER. Dr. Breslow could I interrupt you just for a moment to welcome Mr. Beilenson, who particularly wanted to hear you.

We just started 30 seconds ago. I would like to turn the chair over to you, Congressman Beilenson, to make any remarks——

Mr. BEILENSON. I don't have any remarks to make, except that it is nice to see the doctor here.

Mr. SCHEUER. Why don't you take charge?

Mr. BEILENSON. Thank you. I am now in charge of you Dr. Breslow. [Laughter.] Please proceed, sir.

Dr. BRESLOW. I can recall a time when he was in similar charge in the California legislature, and I am pleased to see him in charge in the Congress.

Mr. BEILENSON. It's only for a couple of minutes.

Mr. SCHEUER. He's doing a superb job here, and you and all the people who helped to educate him should be very proud of your product.

Dr. BRESLOW. That's right. Thank you.

To continue what I was saying, the use of the CAT scanner, electronic fetal monitoring and coronary bypass surgery already exceeds what can be scientifically justified, as discussed in the report, and at a total cost, now or soon to be, greater than $2 billion annually.

There is some use for every one of these technologies. For many cases of cancer of the uterus, hysterectomy can be life saving, and definite health benefit comes from certain applications of the other procedures mentioned.

The problem lies more in the failure to assure appropriate use of technologies with some demonstrable benefit than in the use of those with no value.

Now, I have cited in the testimony—I'd like to direct your attention briefly on page 3—seven steps which, it seems to me, we should give attention to in examining the question of how we proceed from research in medicine to application. These are so important that I would like to go through them briefly one by one. They are taken from the OTA report. And they were adapted from the report of the President's Biomedical Research Panel.

First, there is discovery through research of new knowledge; second, translation of that new knowledge into new technology, development of a strategy for moving the technology into the health care system; third, evaluation of the safety and efficacy; then development and operation of demonstration and control programs to ascertain feasibility for actual practice in the community; next, diffusion of the new technology through a process of increasing acceptance into medical practice; then education; and seventh and finally, skillful and balanced application of the new developments to the population.

Now, what we have been doing in America is to support reasonably generously step one, and, to some extent step two. With regard to the seventh step, we have been supporting the application of technology to excess rather than in a skillful and balanced way.

Unfortunately we have been neglecting the second half of the second step as well as the third through the sixth steps. We have largely ignored them. We have abandoned them to so-called marketplace forces.

We have not tried to deal with those steps until very recently, and then only halfheartedly in a rational way.

The drive to technology resulting from research—there can be no questions about that drive—coupled with the pull generated by our system of medical care toward application whether justified or not, has led to the imbalance that now occasions your consideration of this topic.

Let me give a couple of examples. I happen to have been involved in the "mammography controversy" when the National Cancer Institute re-examined its position with respect to the use of mammography in demonstration programs for breast cancer detection.

Examination of the only scientific study of the issue disclosed that breast cancer detection, including mammography—that is, X-ray diagnosis of the breast tissue—was effective in women over 50. There was no evidence of effectiveness in women under 50, and there was some risk for such women.

Yet tremendous pressure was exerted to ride over the obvious evidence and to extend routine screening with mammography to younger women in the absence of demonstrated value and in the face of some risk. Although references were made to new technology, there was no commitment to ascertain whether the alleged new developments in the technology would yield any benefit that had not appeared in the original study.

Only after rather stormy controversy and national conferences was the National Cancer Institute sponsorship of application to women under 50 stopped.

I think it is to the credit of the NCI that it did undertake that kind of reexamination. In other elements of the health care system such control has been less complete.

American women have been unfortunately confused about a technology that does have some value if they are over 50, and even in certain cases under 50, but not for routine screening.

We do not have what the OTA report and others now call for, development of a strategy for moving the technology into the health care system.

Mr. SCHEUER. Would not that imply both scrutiny of efficacy and scrutiny of efficacy at what cost, the whole cost-effectiveness concept?

Dr. BRESLOW. Certainly. But before you can turn to the cost-effectiveness issue, you must first ascertain whether it is of any effectiveness to women under 50.

Mr. SCHEUER. Of course.

Dr. BRESLOW. So here we were in the position of providing routine screening to women under 50 in the face of clear evidence that it did not have any benefit to such women; in fact, imposed some risks on them. That is an example of where the waste has been occurring, Mr. Scheuer.

Mr. SCHEUER. That really is a cost-benefit analysis simply saying there really is no benefit whatsoever, so let's not go into it any further.

You have a tougher judgmental challenge when there is some benefit at a very great cost, or when you get into all these moral and ethical questions we have been wrestling with, than when there is no efficacy whatsoever. A preliminary cost-benefit analysis is easy when you say there is no benefit.

Dr. BRESLOW. That's right, but we ignore those studies; that's the point. We're wasting a tremendous amount of money because we have been not focusing sufficiently on the first questions; and that is: Does it have any benefit? That is the first question.

We're in the midst of a couple of situations that are rather similar: the CAT-scanner and coronary bypass surgery. Both appear to offer some benefit, but far less than would justify the proliferation of the technology that is taking place.

The CAT scanner has value in diagnosing certain problems in the head, the cranium, but its value in other parts of the body has yet to be clearly demonstrated. Yet we have rushed in to purchase a great number of scanners, both body and head, with expenditure rapidly escalating toward $1 billion annually.

You were asking, Mr. Scheuer, a few minutes ago about other countries and their use of technology.

It happened that just earlier this week, we had as visitor at UCLA a professor of social medicine from Sweden. I asked him—and he is quite knowledgeable about these matters—how many CAT scanners they had in Sweden. There are almost 8 million people there.

He said he was quite sure that they had three head scanners, and no more than two body scanners. He wasn't sure that both of them were in operation.

Then I asked him, what he would propose that we have in California where we have 22 million people. He said, "well, I think perhaps you should have 5 or 10."

And I said, what about 15? No, that would be too many, you couldn't use that many, because the use of the body scanner, he explained, now should be only for investigational purposes. Let us find out the efficacy of it first. He acknowledged that there was use for the head scanner.

Mr. SCHEUER. Well, when are you going to drop the other shoe? [Laughter.]

Dr. BRESLOW. Excuse me for taking so much time.

Mr. SCHEUER. I want to know how many CAT scanners they have in California.

Mr. BEILENSON. It's better this way, drawn out a little.

Dr. BRESLOW. I asked him, what about 50. He said, "oh, no, no." He said, "you're joking." I said, "no, how many do you think we have in California?" He said, "well, it's such a rich place—he'd been driving around Los Angeles—I suppose you may have almost 100, but that would be way too many in California."

So I said. "the fact of the matter is that we have more than 200 in California." Most of them now are of a nature that they can be used for so-called body scanning in the absence of any clear-cut evidence that they have any substantial value.

The other day I happened to be in a meeting called by Governor Brown to discuss this matter of cost containment.

Mr. BEILENSON. How is he these days?

Dr. BRESLOW. He was fine that day.

He went around the table of several of us whom he had assembled to advise him and his administration on what could be done within the State to control the cost of medical care. When it got to my turn in this first interchange, I mentioned that CAT scanning in California was now becoming an industry of more than $100 million. And I asked the Governor what he would say if his director of health care—he has an excellent director of health—were to come to him and propose $10 million for a new preventive medical

program that we knew would be doing some good, and what would he say if she came to him and proposed a $100 million program that would also be doing good and could demonstrate it.

He shook his head in disbelief that we could soon be spending $100 million on CAT scanning in California.

So I did the arithmetic for him. I didn't know exactly how many CAT scanners were in operation. They told me that there were more than 200. I pointed out that for economic operation of CAT scanners you must now do, so the experts say, at least about 2,500 scans per year.

Then I asked the health planners, of whom there were many in the room, whether any of them knew of a place in California where you could get CAT scanning done for less than $200 an examination. Nobody knew of such; for the most part it was considerably more.

Multiply 200 times 2,500 times $200, and that's very conservative, and you come out with $100 million.

We're making decisions like that in our health care system all the time without even taking note of them. And then when we come to propose something rational in the way of more preventive services we are challenged because it is going to cost $1 million or $10 million or some "tremendous" amount of money.

Would it not be preferable for the Federal Government to ascertain the value of body scanning—about which there is really very serious doubt, and considerable question that it has any substantial benefit—before launching widespread use of that technology? Would it not be worth a substantial investment of time and money, especially when Federal tax dollars are going to be used to pay for a large portion of the cost?

What inhibits that approach and instead places at least 5 to 10 times as many CAT scanners in operation as can rationally be justified now? I believe that the answer lies in our recent historic tendency to rely on medical technology for health, to the point of not paying serious attention to questions about its particular values, and our willingness to pay the bill no matter how much waste is involved.

I realize that health planning and peer review and other ventures have been initiated to deal with such problems. None of these ventures have yet been successful. Meanwhile the problem is growing. At some point, I believe that the Federal Government should refuse to pay directly or indirectly for applications of medical technology when efficacy is in serious doubt.

At the same time, the Federal Government should commit itself to substantial support for developing an appropriate strategy for those steps, three, four, five and six, that we almost always neglect in the progression—not "always" but almost always—in their progression from medical research to useful application.

That would save money and also benefit health.

Mr. Beilenson. Thank you very much.

You spoke earlier about not having done much for steps three through six, but having abandoned them generally to the marketplace forces. That's been a problem, hasn't it, with respect to all kinds of health problems?

I mean the marketplace, the usual competitive marketplace, doesn't seem to apply to a health system, when we're talking about hospitals, new medical technology or anything like that.

Dr. BRESLOW. The fact that there are third parties between the providers of technology and the persons who are to benefit, the patients, may enter into the equation one way or another.

Mr. BEILENSON. There's almost an unlimited demand for health services, especially if someone else is going to be paying for it—which, I guess, is another way of saying what you're saying.

You mentioned that we have as much as 5 to 10 times as many CAT scanners in operation as rationally can be justified now. Are people still acquiring them? I mean, is it going to be 10 to 20 times as many soon, or have we reached the number that people are going to acquire?

Dr. BRESLOW. Well, there may be some slowdown in the purchase of CAT scanners—I hope there is—by hospitals because of health planning requirements, and greater and greater attention to this issue of purchase of technology by institutions. But there is nothing in law or practice now which inhibits the purchase of CAT scanners by physicians to operate privately.

So we are having a proliferation growing in that sector of the health industry.

Mr. BEILENSON. That's continuing?

Dr. BRESLOW. That's continuing.

Mr. BEILENSON. I don't really have, myself, any questions to ask you. It's wonderful that the committee invited you to be here today. There is no one I know of in the country whose involvement with public health questions have been more thoughtful or useful than your own. It's gratifying that some of the people here who have not perhaps been exposed to you berfore have had a chance to meet you and to hear from you.

I think either of our two gentlemen up here may have some additional questions for you.

Dr. MURRAY. Dr. Breslow, Dr. Russell mentioned kidney dialysis, and there was some discussion about relative merits and relative costs, and some question about what incentives there were for home dialysis versus center dialysis and what balance of merit there might be.

I did not respond at the time, but I was reflecting on a related conversation that I would like to offer for your critical judgment.

The conversation came about with a doctor connected with the University of Maryland Baltimore Hospital Kidney Dialysis Clinic.

He said that in his personal experience—this is a small sample, you understand—but he had the impression that people who dialyzed at home tended to do better as patients.

He raised, thereby, the corresponding question about the large experience, the regional or national population of people dependent on kidney dialysis. Do we know whether patients who dialyze at home tend to do better; if we do, if we have evidence this is the case, do we have any way of separating the factors and answering the finer questions for determining what we should do about it?

Dr. BRESLOW. I'm not an expert in kidney dialysis, and so I really cannot answer your question.

I am sure that there is evidence on this matter. I am simply not aware of it, and I don't like to be offering speculation on things that I really don't know.

I would make one remark, however, about the problem, that you may think a little peripheral to the issue you are raising, but it may be pertinent. An increasing number of studies, including one that we have been carrying out in California now for some years, indicates that people who have strong social support systems do better in health and in their mortality experience than do people who are alienated from social support systems. Thus people that do have live-in situations with families and with friends and others who give them social support may tend to do better for that reason.

Whether this applies in the particular case of dialysis, I simply could not say because I do not know the facts of the matter. But it is a general health principle that people who have strong social supports do better than those who don't.

Dr. Murray. I would like to move from the more specific, which is kidney dialysis, to a more general area. Kidney dialysis is only an example of a general problem.

That is, we have a substantial body of traditional practices, as well as a substantially growing body of newer practices for which cost-effectiveness or effectiveness scrutiny has not been adequate. Safety and efficacy apparently are in question for some procedures that have already been around for quite a while.

I'm sure that all of us would like to see every on of our procedures, devices and techniques now given the kind of thorough technical, medical scrutiny that they deserve, and in addition to that perhaps some economic scrutiny as well.

But the first part of that, the purely medical evaluation, looks like a task so enormous that no one group, one agency—in fact, the whole Federal Government, perhaps could not undertake it.

On the other hand, if there is no single body that could be named that might undertake it, could we consider that the whole health system somehow in concert might engage in this enterprise?

First of all, is that a reasonable suggestion; and, second, if it's anything like accurate or reasonable, how would we go about getting such a thing started?

Dr. Breslow. Let me respond to what I think is meant by your question by using the CAT scanner as an example.

As of a couple of years ago, and still at the present time, there was general agreement without having the kind of clinical trials—but sometimes we don't need those clinical trials to arrive at judgments—that the use of the CT scanner for intracranial problems was justified.

Thus we were in a position of using and paying for the CT scanners applied to head injuries, brain neoplasms and vascular disturbances and the like. The diagnosis of these can be aided considerably by CT scanning.

Then came the further development and attempted application of the CAT scanner to the rest of the body, particularly to the abdomen.

There was no significant evidence as of a couple of years ago, nor to my mind still, in favor of using the CT scanner to anything like

the extent that is now being implied in the machinery purchased, and in the people trained and employed.

It seems to me that it would have been desirable two years ago, and even desirable today, before the Federal Government embarks upon paying for CT scanning of the body, to establish a commission to ascertain its health value.

I would think that it would be sensible for Blue Cross and Blue Shield, and the private insurance companies, at least the large ones, to join with the Federal Government in this enterprise.

Dr. WELLS. May I interrupt at that point.

Is there any indication that something like this might be happening?

Dr. BRESLOW. It's been suggested; whether it's going to happen or not, I don't know.

Mr. BEILENSON. Those scanner problems can be sad. Everybody knew 2 or 3 years ago that we weren't sure, perhaps, of its usefulness and the efficacy. Everybody was aware of the huge cost that was involved and we weren't sure what the benefits might be, whether they would be balanced off, and we're still not sure.

Often-times things creep up on you and you are not aware until later that you have made a serious mistake, but we all knew.

Dr. BRESLOW. There may still be time.

The point is, I would propose such a commission be established and be charged with making a proper study of the use of the CT scanner for the body to define its limits, and even to suggest the number of scanners, considering the volume of services that would be justified on the basis of the study which they would undertake.

I would propose that the Federal Government, hopefully with Blue Cross/Blue Shield and the private insurance companies—but alone, if necessary, because it would certainly be worth it—fund such a commission to carry out such studies on whatever scale the commission determines to be necessary.

Obviously this would have to be some kind of a cooperative clinical trial involving 5, 10, or 50—whatever number of institutions around the country that would have the competence and would be willing to enter into a national evaluation.

We've done this type of thing before. It's not entirely new.

And none of the insuring parties would pay for the body scanning on a fee-for-service basis until the evidence were in. In the meantime, they would fund completely the appropriate study to be carried out in whatever places were necessary to get the evidence.

Now, some people possibly would benefit from this study. On the other hand, we don't know that they would at this time.

Mr. BEILENSON. It's my understanding that the Department of Health, Education, and Welfare has recognized the need for some improvements in this area and has taken some steps toward assessment of new technologies, and toward technology oversight within the Department. I think there is some kind of de facto group set up under Dr. Richmond, that has become involved in this.

I think parallel legislation recently passed the House which—I don't know if anyone is familar with what Dr. Richmond and HEW is doing an with that legislation, but if they are, either you or subsequent witnesses, perhaps, could give us some feel, or evaluation as to whether those steps might turn out to be useful steps.

Dr. BRESLOW. I know that Dr. Richmond and others in the Department of HEW are concerned about this problem, that they have been undertaking within the Department to get some enterprise started along these lines.

And I know also that the House has passed a bill and the Senate has passed a bill, and that may be those two pieces of legislation will eventuate in some congressional action to support that kind of a system.

What I am saying here is merely one indication of the very great importance attached to developing that kind of a system, for developing strategy on major pieces of medical technologies that are coming along.

We have the opportunity—we have had, as you have indicated. For 2 years, we have seen the problem coming; we know what it means. We haven't yet done anything about it but I hope that we will.

Like you, I do see the beginning efforts, and I am very hopeful about them.

Mr. BEILENSON. I think, Doctor, that we have no further questions, but I would like to tell you again how wonderful it is to have you here testifying and to see you again.

Our next witness is Dr. Donald A. Young from the U.S. Veterans Administration scholars program.

Dr. Young, thank you very much for letting us take a few minutes of your time to visit with Dr. Breslow.

[The prepared statement of Dr. Donald A. Young, M.D., U.S. Veterans Administration scholars program is as follows:]

Statement by

DONALD A. YOUNG, M.D.

Subcommittee on Domestic and International
Scientific Planning, Analysis and Cooperation

Committee on Science and Technology
U.S. House of Representatives

September 27, 1978

I am Dr. Donald Young and I am currently associated with the VA Administrative Scholars Program sponsored by the Veterans Administration and George Washington University. However, I testify today as an individual expressing my own views.

I am pleased to be able to discuss with you some of the complex issues related to health technology, especially the problem of making technology more productive for the individual, the community and society. Health technology, as I am using the term, is the tools used for health care. Included are machines, procedures, skills and knowledge.

There is great interest in improving the federal government's ability to assess and evaluate technologies and to develop strategies to promote more effective use of them. Much of the responsibility for conducting and coordinating technology assessment and evaluation activities will most likely be assigned to an Office of Health Technology. Yet, wide and sometimes divergent views have been expressed concerning the goals and expectations for technology evaluation and the responsibilities that should be assigned to an Office of Health Technology.

To resolve these divergent views, clear policies need to be developed regarding three issues:

1. What is expected from the process of technology evaluation and assessment, that is, what are the goals of the process? After all, if you don't know where you are going, it is unlikely that you will get there, no matter how hard you try.

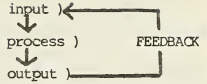
2. How is the technology evaluation process going to be managed and administered within the federal government? Which agencies, besides the Office of Health Technology, will be given the responsibility for funding and generating new information, coordinating existing activities and linking the results of technology evaluation to actions by other federal agencies and the private sector. Should technology evaluation activities be limited to comprehensive examination of a few highly selected technologies or include as well less comprehensive evaluation of a large number of technologies.

3. How much and what kind of federal government intervention should there be in all stages of health technology development? Where should the responsibility be placed for developing and implementing the intervention mechanisms?

Functions

I am going to use a very simple functional schema as a framework upon which to hang health technology management and policy issues. Technology management can be divided into four major functions:

1. Information must be obtained
2. Information must be processed
3. Information must be put out
4. The sequence should be subject to feedback and change



There are a large number of institutions and people that play an important role in one or more of these functions. (See FIG.1) It is my view that the way in which these four functions are managed and the coordination between agencies, people and roles is essential to the more productive use of technology.

I would like to examine more closely the four functions and indicate some of the problems faced by the managers of the technology process and some of the policy questions which these problems will raise.

Input - Data Base

On the input side, it will be necessary to establish as complete an information base for decision making as possible. Information must be obtained concerning the safety and efficacy of new and existing technologies, the direct and indirect cost of technologies (capital and operating), the primary, secondary and tertiary impact of technologies and the level of technical and health care delivery consensus regarding need and appropriateness of technologies.

A second input requirement is for data indicating where the needs are greatest for technology evaluation activities or technology related information. Different sources will undoubtedly indicate different high priority needs. Unfortunately much of our statistical information is not in a form that can provide maximum assistance in needs assessment.

It will be necessary to develop management mechanisms to receive and organize a very large volume of information, much of it in a form and format not readily usable. For example, between January 1977 and June 1978, 251 papers were published in the scientific literature regarding coronary artery surgery. Many of these papers contain conflicting conclusions and recommendations and most do not relate their findings to the practical problems of physicians, industry, federal regulatory and reimbursement agencies.

Much of the necessary input information will flow readily from sources such as the NIH, NCHSR, NCHS, HCFA, FDA, academic health centers, professional and voluntary agencies, and industry. However, it will be necessary to develop procedures to search out information that does not readily flow in and to generate new information. Although technically difficult, if adequate resources are provided and responsibilities are clearly assigned these aspects of technology should not present major management problems.

The greater problem will probably not be information overload, but information which is insufficient or only marginally adequate for sound decision making. This deficiency stems from the absence of both basic and applied knowledge in many health care areas and an even more fundamental problem, the absence of proven methodologies or tools to gather the knowledge.

The question has been asked, "if science and technology can put a man on the moon, why can't it cure cancer or diabetes or heart disease?" And the answer, I believe, is that the space effort required only the resources, energy and commitment to apply existing basic knowledge to the problem. In the search for the cure of many diseases, there yet remain too many holes in basic knowledge. Despite great needs, there are some puzzles that science simply cannot solve at the present time.

In a related vein, it is frequently asked who should have a tonsillectomy and who should not, or how many blood tests should be performed on a given patient or when should a CAT scan procedure be done? Despite extensive research on cost, efficacy, and utilization of these and many other procedures, there remain large gaps in the information base upon which technology decisions will be expected.

Additional empiric data (facts) regarding safety, efficacy and the costs of procedures and devices can be developed but data on the impacts of the technologies on the public as a whole or questions such as the value of individual procedures in relation to other components of the health system will be much more difficult to obtain, because value judgments as well as facts are involved.

Ethical and value judgments are not amenable to scientific investigation, yet decisions cannot be made without considering these ethical and value questions. For example, there is a large amount of information, empiric and normative, concerning chronic kidney dialysis, yet conflicting and ever changing opinions exist about who should receive chronic dialysis and who should not. Who should make these decisions? Should the procedure be done in the home or an institutional setting? Should reimbursement depend on setting?

The Office of Health Technology will have to deal with a wide array of value judgments related to the technologies being examined. These judgments will inevitably produce conflicts and ways must be found to resolve the conflicts and reduce the tension produced.

When information bases are not adequate for decision making, new knowledge can be generated. This will present less of a problem if the responsibility and resources to accomplish the task are assigned to the Office of Health Technology. Depending upon other managers, agencies and budgets to generate new information, however, presents

problems of no small magnitude. If the responsibility for knowledge generation resides in another agency of DHEW, then traditional boundaries in the health bureaucracy must be crossed. The needs and goals of high priority to the Office of Health Technology undoubtedly will not coincide with those of knowledge generating, program or regulatory agencies. It is reasonable to suppose that each of the other agencies will struggle to meet their own organizational goals and respond to technology evaluation needs only if time and resources allow.

For example, the Office of Health Technology may wish to examine in depth the use of respiratory therapy in the care of the patient with emphysema. After surveying the existing data base, information may be lacking concerning the efficacy of certain technologies and the reimbursement implications of others. It may be necessary to turn to NIH and HCFA and convince them of the need to support research to fill the gaps. They in turn may regard the needs as relatively low in priority for their time and resources. Using the power and authority of his office and persuasive skills, the manager can attempt to negotiate to resolve the conflicting priorities. If unsuccessful, department-wide leadership may be necessary to solve problems of institutional jurisdiction. In any case, personal and bureaucratic tension can be expected and the manager must be prepared to deal with and resolve the tension. Using different power and authority, the

the manager will also find it necessary to negotiate with the private sector, industry, professional societies, and academic health and policy centers to obtain information needed.

In determining needs for technology assessment and evaluation, widely conflicting input data is to be expected. To successfully process the conflicting information, the source of the conflict must be sought and understood. For example, a strong need might be stated for Federal standards regarding indications for tonsillectomy while another view would be opposed to efforts to develop Federal standards for any surgical procedures. Understanding that the first view is of those concerned with costs of "unnecessary" surgery, and the second those who feel it is the physician who must determine the standards of his practice would give additional understanding of the conflicting opinions and assist in the subsequent processing of the data.

Health technology managers will be continually confronted with the need for decision making in the absence of complete data. There will be significant pressures to produce decisions where needs are great but information is conflicting or incomplete. However, as the information upon which decisions are made becomes marginally adequate and more controversial, the results of the technology evaluation process will become more controversial and less useful.

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Process

Having received a large volume of technology related information, that information must be processed. It must be put into a form that is useful for technology policy decisions and useful to others if a clearing house function is established.

The purpose and goals of technology assessment and evaluation must be explicity understood before relevant information processing can take place. Is the function primarily to generate, search out and compile new information or in addition to somehow screen, analyze, translate and transfer it in a form that is valuable to others? Is it expected that technology evaluation will go to the next step which is drawing inferences and conclusions from the information and developing criteria and standards for technology development, utilization and reimbursement? If this latter function is expected how and where should it be done, within the Office of Health Technology, within other HEW agencies, with the cooperation and consultation of the private sector, etc.?

The policy options chosen to guide the technology evaluation process will determine the problems with which managers will be faced and the skills necessary to deal with those problems. In any case, diverse interests and competing forces will be attempting to mold the process. The manager must be attune to these forces and understand their motivations and viewpoints to function most effectively and efficiently.

An additional very signficant management problem in processing information is created by the extreme complexity of many issues. For example, if coronary artery bypass surgery were to be chosen for review, a very large amount of scientific data, some of it conflicting, would have to be examined, cost benefit and cost effectiveness data would have to be gathered. New information regarding social, economic and ethical impacts of the procedure on patients, families, surgeons and hospitals would have to be generated. Finally, value judgments would be necessary. If the economic costs and benefits of the procedure were known, and if the outcomes could be predicted with certainty and if the societal impacts were clear, how can it be determined if the procedure is "of value" and to whom should it be "of value" - the patient, his community, society as a whole? Who should make these decisions and how should they be made?

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Output

The Office of Health Technology will put out information. The information disseminated will differ in form and format from that received, reflecting the processing which has occurred.

One output function will presumably be to package information for other agencies and groups who will use it in their decision making. It is, therefore, necessary to identify the targets for the information so that packaging is appropriate to the target. Targets could include program agencies, regulatory agencies, planning agencies

at all levels, medical practitioners, scientists, industry, etc. Yet the fragmentation of responsibilities among private and public organizations will make it very difficult to package and appropriately target the information. It must be decided to whom technology related information and decisions will be transferred.

Unfortunately, putting out information does not always result in desired changes in behavior. If users have indicated a need for the information and if they feel they have contributed to the processing, the information is more likely to be accepted and acted upon. Still, in many instances, this will not be sufficient and some form of intervention mechanism must be brought into play. The form, purpose, and organizational responsibility for the intervention is critical to the technology evaluation process. If the intervention takes the form of regulation which is in conflict with the norms and values of the public, practitioner, scientist, industry, etc. there may be significant hostility, lack of cooperation and possibly overt obstruction to the whole process of technology evaluation. It is essential that the agencies responsible for implementing intervention mechanisms be clearly indicated and their relationship to the Office of Health Technology clearly spelled out.

Besides the problems which could occur as the result of policy decisions regarding intervention mechanisms, there are other output problems with which the manager must deal. At times there will be a

conflict between the agency's administrative goals (e.g., decreasing costs or meeting the needs of other federal agencies) and outcome goals (e.g., improving delivery and quality of care.) Administrative goals may suggest a certain type of information packaging, choice of targets and intervention strategies while outcome goals may require quite another. For example, a situation may arise when because of limited resources, it is necessary to choose between supporting studies which could help reduce Federal health costs related to reimbursement and studies promoting the development of a new and expensive diagnostic technology.

An additional major difficulty with information dissemination is that understanding of the transfer process and the techniques of processing information for dissemination are still at a very rudimentary stage. Much more must be learned about how to effectively transfer information so that it will be appropriately used.

Feedback

Finally, the sequence of information input, processing, and output should be iterative, that is at all stages the opportunity must be open for feedback and additional rounds of processing. This is necessary to develop further information where the base is insufficient for decision making, to obtain informed reaction to prior decisions and to permit rapid change as new information is developed and processed.

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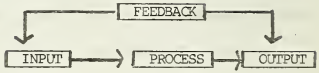
The technology evaluation process itself must be open to change. The lack of knowledge and experience and the rapid changes in technologies indicates that the manager will have to maintain a dynamic process subject to continued upgrading and improvement and capable of quickly correcting past errors.

I thank you for your attention and would be pleased to attempt to answer any questions.

FIGURE 1
CONTRIBUTORS TO THE TECHNOLOGY
MANAGEMENT PROCESS



RESEARCH AGENCIES			
ACADEMIC HEALTH CENTERS			
SCIENTISTS			
PHYSICIANS			
PROFESSIONAL SOCIETIES			
VOLUNTARY SOCIETIES			
INDUSTRY			
PROGRAM AGENCIES			
REGULATORY AGENCIES			
PUBLIC			

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TESTIMONY OF DR. DONALD A. YOUNG

Dr. YOUNG. I am currently associated with the V.A. Administrative scholars program sponsored by the Veterans' Administration and George Washington University. However, I testify today as an individual expressing my own views.

As a physician in medical practice, I have been a user and prescriber of health technology. As the medical director of the American Lung Association, I was involved in development of criteria and guidelines for the use of technologies by others. And currently I am conducting a study on technology dissemination, including examination of the organizational, administrative and management aspects of technology.

These experiences have left me with a good deep appreciation of the great complexity of technology-related issues, and of some of the problems that might be faced by an Office of Health Technology as it begins its work. I would like to examine some of the functions that the Office of Health Technology might be engaged in, and to suggest some approaches to look at the problems and suggest solutions.

The first function is to receive information, an input function. The Office of Health Technology will receive a rich variety of input data which will be used to make decisions. These data will deal with medical information, including efficacy of procedures and technologies, but it would also deal with economic, social, and ethical inputs. In addition, data will be necessary to determine where the needs are greatest for technology evaluation activities.

Management mechanisms must be developed to receive this information, to organize it, to process it, and to put it into a form in which it can be utilized for decisionmaking. Much of the information will readily flow in; however, procedures will have to be developed to search out information that does not readily flow in. This information may come from other Federal agencies, from industry, from professional and voluntary groups.

The greatest problem, however, will not be by the large volume of information, but, rather, information which is not sufficient or which is only marginally adequate for making decisions. For example, if coronary surgery were to be examined, there were during an 18-month period, 251 different publications in the medical literature regarding coronary artery surgery; of these 251 publications, many came to conflicting conclusions and to differing recommendations.

The problem with marginal or inadequate information is related to several factors; one is gaps in knowledge. There are simply some puzzles that science cannot yet solve despite great need. Another problem is related to gaps in health service delivery knowledge; the effects of reimbursement on physician behavior; the effects of planning decisions on the uses of technology. We simply do not have information in many of these areas. The third, and perhaps the most important, is the lack of ability to sort out and to weigh value judgments.

A fair amount of time has been spent in the past 2 days on the question of value judgments, "Who will make them and how they will be made". For example, again, in coronary artery surgery, one nationally prominent heart surgeon has stated in an editorial in

the Journal of the American Medical Association that clinical trials are probably not necessary to evaluate coronary artery surgery. And he has gone further to say that even at the cost of $10,000 or $12,000 a procedure, they are a bargain.

These are clearly value judgments of one individual. Others disagree with these judgments. How will these judgments be weighed; what criteria will be used to weigh them; whose judgment will be most important?

The National Institutes of Health, through the consensus development program, has gained some experience in weighing value judgments, particularly value judgments in regard to medical and technical aspects of procedures. There's very little experience, however, in weighing value judgments in regard to social and ethical beliefs and how to weigh these.

Research will help us to understand better the fundamental mechanisms of disease and will fill many gaps, but time will be necessary. If resources are allocated and responsibilities are clearly assigned, additional empiric data can be generated regarding health services delivery, safety and efficacy of technologies.

Ethical and value judgments, however, are not amenable to scientific investigation, although some attention has been given to this. It may be that the Office of Health Technology may make a significant contribution by promoting research to improve the decisionmaking process when ethical and value judgments are necessary.

To this point, I've stressed the importance of the raw data (medical, economic, social, and ethical) that will assist in decisionmaking regarding technologies.

I've done this because I believe the success of the Office of Health Technology will be dependent on these data. The Office will be under significant pressure to produce results. However, as information upon which decisions are made becomes more controversial and less adequate, it's likely that the technology management process will also become more controversial and the results may well be less useful.

I'd like to turn now to "process", that is, to handling of the information as an Office might handle it. Much of the data that the Office of Health Technology will receive will not be in a form that's useful for policy decisions, useful for actions. It will be necessary to sort the information, to integrate scientific and research facts with beliefs and values from diverse groups and put all this information into a form from which technology policy decisions can be made, action plans developed, and intervention strategies developed.

Before relevant processing can occur, however, the goals and purposes of technology evaluation and assessment should be clarified. For example, would the OHT be responsible primarily to search out, screen and compile existing data, or, in addition, would it be responsible for generating new information? Will it generate the new information itself, or primarily recommend that other agencies do?

If it is to recommend that other agencies generate the information, it would have to cross traditional boundaries within the health bureaucracies. How will these linkages with other agencies

occur? Should it go beyond generating information to synthesizing the information, that is, draw inferences and conclusions from it; set guidelines, or criteria, or standards for care, or for medical practice, or for reimbursement? If the Office of Health Technology responsibility stops short of setting standards and short of intervention decisionmaking, then where will this occur?

It's my opinion that clear policies need to be established regarding the extent of responsibility for the Office of Health Technology and the relationship of this Office to other agencies. Even if the medical benefits of the procedure are known, the costs are known, the societal impacts can be predicted clearly, how is this information going to be used to make reimbursement decisions; how will it be used by planning agencies at the national, State, and local level, by PSRO's?

In other words, if recommendations are made, what will cause them to be acted upon?

One way is for the manager within the Office of Health Technology to foster coordination by using persuasion and negotiation. He may sit down with agency heads and try to resolve a conflict in priorities for research, or a conflict in priorities for attention to other areas. Second, he may use the power and authority of his office or of the Assistant Secretary for Health, though it may require HEW-wide leadership to implement recommendations that come from a technology-management process. In addition, there are some new and nontraditional managment mechanisms which can be used to facilitate this type of cross-organizational cooordination. Consideration should be given to examining these management mechanisms to better foster this cross-agency coordination.

The last function is output. The information that the Office puts out will differ in form and format from the raw data which it receives, reflecting the processing that has occurred. If the information is to be used by other groups in their decisionmaking, then the targets for it should be indicated. For example, the information used by planning agencies may require a very different format than information used by a medical practitioner, or a professional society, or a voluntary agency, or a reimbursement agency.

Putting out the information, though, may not be sufficient to result in changes in behavior. Some form of intervention mechanism may be necessary. If an intervention mechanism is necessary, where is it to be carried out; what agencies are involved; how are they related to the Office of Health Technology? I think the decisionmaking is a two-way street.

If the Office of Health Technology is considering an issue that has reimbursement implications, it may be well to involve people from the reimbursement agencies early on in the process. This would accomplish two things: One, the recommendations are more likely to be supported; and, second, understanding the problem after having gone through the exercise of technology evaluation may well help them design interventions that are more appropriate to the problem.

A final output problem which I think is a very significant one is that understanding the transfer process is at a very rudimentary stage. We simply have very little information on how knowledge is disseminated; how technologies are disseminated. Much more needs

to be learned about how to effectively transfer information so that it will be used appropriately. It may well be that the Office of Health Technology would want to devote a significant amount of its attention to this difficult problem.

Finally, the three functions should be subject to feedback. The sequence should be iterative and there should be opportunity at all stages to open up decisions for reexamination as new information comes in and for additional rounds of processing.

In conclusion, the issues regarding technology assessment and evaluation are very complex, and I don't think that quick results will be forthcoming. In my view, the way that the functions are managed is essential to the success of technology evaluation and assessment. And, more importantly, to the implementation of recommendations that emerge from the process.

It may be that in 2 or 3 years, as we look back on the accomplishments of the Office of Health Technology, that significant contributions would come not only from examining technology but from improvements in methodologies and tools for the evaluation of the technologies and development of mechanisms to insure coordination of activities within Federal agencies, and the linking of these activities to the public sector.

I'd be happy to try to answer any questions you have.

Mr. BEILENSON. We thank you very much for your testimony. Mr. Chairman, I don't know if you have any questions.

Mr. SCHEUER. No, I don't. Thank you very much, Doctor.

Mr. BEILENSON. Dr. Murray?

Dr. MURRAY. Dr. Young, I was particularly pleased to hear you suggest that some of the other divisions of HEW might be brought into the assessment process.

I recognize in that suggestion that, while it might not involve one of the new management mechanisms that you spoke of to foster cross-agency coordination, it does seem that getting partners to come into the original act of assessment could, indeed, be a stimulus to giving them a stake in the whole idea of technology assessment, and in the idea of doing something as a result of assessing—what sort of strategy or plan might come out of it.

Did you have other management mechanisms—you said there were new management mechanisms to foster this?

Dr. YOUNG. Yes.

The traditional organization has a boss and a series of employees. Those employees then are bosses to another layer of employees, and on and on in a pyramid structure.

During the 1950's and 1960's, as the electronic industry expanded and the space program expanded, they required organizations and industry to develop new techniques. A different management structure came into being in many organizations called the matrix.

The problem in the space industry and the electronics industry that led to the development of matrix was that you had traditional line functions and staff functions.

The line management needed staff functions such as research support, development support. The staff individuals were put under pressures from a variety of line managers and didn't know to whom to respond first, where to put his priorities. In addition, he had other functions given to him by his boss.

To try to solve this the matrix was developed which says that one employee will have two bosses, not one boss. He would have one boss as a line manager; for example, a product manager, and another boss who was in research and development. He would report to both bosses. When a conflict comes up in orders from the staff boss and from the line boss, then he gets the two bosses together to resolve the conflict.

Now, in looking at health technology assessment, it may well be—and this could be done informally, it doesn't have to be done formally—an individual would report to somebody in the Office of Health Technology and somebody in the National Center for Health Services Research, and that individual would be the link to technology management activities.

And when it turned out that the National Center for Health Services Research should be involved in new research that was in their mission, he would be responsible for communicating and facilitating activities.

If the required activity did not fit within the goals of the National Center for Health Services Research, then he would have to get the two bosses together to attempt to negotiate a conclusion. It turned out in practice that this could be done quite readily and only occasionally did they have to go to the next higher person to help set priorities.

So that's a type of management mechanism that could foster linkages between two organizations with two different goals, different resources, different priorities.

Dr. MURRAY. I also noted that you mentioned the word "iterative," that the process of technology assessment ought to be iterative.

I certainly concur. Technologies could very well be evaluated early and we would simply not anticipate at the time some of the social, or economic, or technical implications that resided in the introduction and spread of such technologies, and only later would we discover "Oh, my goodness there are new problems here that we did not look at." To reinitiate the process of assessment would certainly be a logical and desirable possibility. This also, however, could relate to the process of cross-agency coordination. That is, for instance, if the Health Care Financing Administration noted a problem of reimbursement for a certain medical service, procedure, technique, or device, and if they had the privilege, or if it was expected of them, to approach Dr. Richmond's office, or the Office of Health Care Technology, to request a reevaluation, this would give another reason for cross agency conversations and for interagency participation.

Dr. YOUNG. That's right.

And would have the added advantage of helping to select the intervention that's most appropriate, based on a fundamental understanding of the problem, as opposed to a more superficial one which might come in a series of recommendations for policy option statements.

Dr. MURRAY. I have no more questions.

Mr. SCHEUER. Thank you very, very much, Dr. Young. We very much appreciate your testimony, and we probably will have some

more questions for you, but we will do that by correspondence and hold the record open for a time for that.

We thank you very much, indeed.

We will hear from the last witness this morning, Mr. David Klein, M.B.A., vice president for research and development, Blue Cross, Blue Shield Association.

[The prepared statement of David Klein, M.B.A., vice president for Blue Cross and Blue Shield Associations, is as follows:]

STATEMENT OF DAVID H. KLEIN, VICE PRESIDENT, BLUE CROSS ASSOCIATION, BLUE SHIELD ASSOCIATION ON TECHNOLOGY AND THE COST OF HEALTH CARE

Mr. Chairman and Members of the Subcommittee: I am David Klein, vice president of the Blue Cross Association and the Blue Shield Association, which serve respectively as the national coordinating bodies for the 69 Blue Cross plans and the 70 Blue Shield plans in the United States.

I thank you for the opportunity to appear before you to present our views on technology and the cost of health care. I would like to concentrate today on one aspect of this broad subject—what the Federal Government can do to support the appropriate use of technology in the health care system. In previous testimony before the Council on Wage and Price Stability, (*1*) the Subcommittee on Health and Scientific Research of the Senate Committee on Human Resources, (*2*), (*3*) and the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, (*4*) the Blue Cross Association and the Blue Shield Association have consistently supported the establishment of a national program to promote, coordinate and conduct evaluations of the efficacy and cost effectiveness of medical technologies. We feel that such a program is needed in order to support the efforts of individual providers and other local parties aimed at ensuring the appropriate use of technology in the health care system.

If a technology assessment program is to provide meaningful support for local efforts, then the design of the program must be based on an understanding of their nature and information needs. Therefore, I would like to begin with a discussion of these local activities, which will include a consideration of how they are limited by the lack of information on the cost effectiveness of medical technologies. This discussion will then serve as a basis for our views on the appropriate structure and function of a technology assessment program. In presenting these views, I will pay particular attention to current initiatives by Congress and the administration to establish a Federal technology assessment program.

In its broadest sense—as defined by the Office of Technology Assessment—medical technology includes any technique, drug, equipment or combination thereof applied to diagnostic, preventive, therapeutic, administrative, or patient support purposes. (*5*) Given this definition of medical technolgy, almost every effort made to increase the efficiency of the health care system must have some impact on the appropriate use of technology. In general, however, all of these activities can be thought of as either attempting to control the supply of technological capacity, or attempting to control the actual delivery of services to patients.

SUPPLY-RELATED MECHANISMS

Supply in the health care field tends to create its own demand. Therefore, effective control of technological supply is a critical strategy to promote the efficient use of technology. The principal mechanism for achieving this control is health planning. Health planning activities aim to insure that the supply of local health care facilities and services matches local need. In addition, health planning can control the deployment of some specific technologies—such as CT scanning—which require major capital investments.

Third party payors can play a role in supporting health planning activities. For example, 27 Blue Cross plans have clauses in their hospital contracts tying provider payment to areawide planning decisions. An additional 28 Blue Cross plans are located in States with certificate-of-need laws requiring State agency approval of new facilities, services and expensive equipment.

Another way to impact the supply of technological capacity is by altering health care benefit packages so as to shift resources to more cost effective health care services. For example, the Blue Cross and Blue Shield Associations are currently working on a variety of benefits designed to promote access to services which prevent and/or detect and manage health problems—such as cancer, drug abuse,

and alcoholism—which have serious health consequences. In the case of cancer, the goal is to increase access to screening services which will (hopefully) result in earlier detection and thus less need for more expensive medical services. With drug abuse and alcoholism benefits, we hope to increase access to services which directly treat these root problems, thus breaking the "revolving door" syndrome whereby patients with these problems are repeatedly treated for medical consequences, but not for causes.

DELIVERY-RELATED MECHANISMS

The second major strategy to impact the use of technology focuses on the actual delivery of services. One way to promote the efficient delivery of health care services in general is through the use of certain types of payment methods. For example, by negotiating in advance the amounts to be paid for hospital services, payors can provide incentives for health cares institutions to limit their per diem costs and thus to judiciously use technology. Twenty-six Blue Cross plans are currently using such prospective payment methods. (*6*)

Utilization review is another mechanism which focuses on the delivery of services. By reviewing patient care decisions throughout a hospital stay, hospitals can insure that the services being delivered to the patient are medically necessary. Blue Cross plans support these efforts by offering technical assistance to, and by sharing data with, hospital utilization review committees. In addition, utilization review committees are increasingly becoming a requirement for facilities which provide health care to Blue Cross plan subscribers.

Plans also conduct their own form of utilization review by screening hospital bills and by reviewing in detail bills which reflect questionable admissions, lengths-of-stay, or procedures. Where unnecessary or inappropriate patient care is identified, plans inform providers accordingly and, in extreme cases, may employ payment sanctions.

I have already discussed how health care benefits can be utilized to impact the supply of services. Benefits can also be used to promote more efficient health care delivery. For example, Blue Cross plans and Blue Shield plans are experimenting with benefits such as preadmission testing, which aims to limit the amount of time for which hospitalization is required, and second opinion surgical programs, which will hopefully act as a check on the unnecessary use of surgical procedures.

Finally, third party payors can foster the appropriate use of specific technologies directly by excluding from covered services procedures which are outmoded, redundant or experimental.

The mechanisms which I have been discussing represent a broad, evolutionary, cooperative effort by local providers, payors, planners, government, and other community members. The key words here are local and cooperative. Since health care needs vary among localities, health care services must be designed around an understanding of local conditions. Furthermore, none of the actors in the local delivery system can make significant progress without the cooperation of other actors. Health planning, utilization review, and third-party payment and provider relations activities are most effective when they support each other. In addition these mechanisms must be supported by local providers and must take account of local practice standards.

INFORMATION NEEDS

As this cooperative system of mechanisms develops, each of these activities is hampered by the lack of authoritative, basic data on the efficaciousness and cost effectiveness of specific medical technologies. The determination of the need of a community for either a general technological capacity—such as surgical beds—or a specific capacity—such as CT scanners—requires an understanding of both the extent of various illnesses and symptoms and an understanding of which technologies are effective in addressing these illnesses and symptoms. For utilization review committees to make effective decisions on the appropriateness of the use of technologies, they require similar information.

Third party efforts are also affected by this lack of information. While we experiment with programs to give providers incentives for the efficient use of technology—such as prospective payment—clearly providers often do not have adequate information to make efficient decisions. In addition, if we prospectively exclude a procedure from covered services or retrospectively deny payment because of a utilization review decision, our subscribers may still be liable for payment. Yet we are supposed to be protecting subscribers from the cost of medical care. If we are certain that a procedure is inappropriate, then it is our obligation to educate our

subscribers accordingly. But we are rarely certain because definitive information simply doesn't exist in most cases.

The Blue Cross and Blue Shield Associations have developed several programs to assist plans in gaining the information which they need to make decisions about covered services and to conduct effective utilization review programs. Since 1976 the Blue Shield Association has conducted the medical necessity program. Through this program medical specialty organizations (*7*) review procedures on an ongoing basis to identify new procedures of unproven value, established procedures of questionable current usefulness, procedures which tend to be redundant when performed in combination with other procedures, and which are unlikely to yield additional information through repitition. Since April of 1977, 42 procedures have been identified for which Blue Shield plans are recommended to require justification for payment. Most Blue Shield Plans have conducted programs to inform local physicians of the medical necessity program's recommendations and are beginning to require justification for these procedures.

Another effort of the associations to assist plans in determining which services should be covered is the National Medical Policy Compendium.The compendium, originated by the Blue Shield Association several years ago, is an ongoing survey tool which keeps plans informed on the payment policies of other plans for a variety of specific procedures. With the staff consolidation of the Blue Cross and Blue Shield Associations, a similar tool is being developed for Blue Cross plans.

In addition to these ongoing programs, the Blue Shield Association's Medical Advisory Committee individually reviews certain procedures of particular concern—due to either their risk, cost, or extent of use. Where appropriate, special studies may be performed or commissioned to support the associations and/or the plans in arriving at recommendations and policies. For example, in response to the CT scanner controversy, the Blue Shield Association conducted studies of the impact of these devices on health care costs (*8*) and of the professional and technical input costs (*9*) in order to offer guidance on appropriate payment levels. At the same time, the Blue Cross Association commissioned a study by the Institute of Medicine (*10*) to identify the major issues surrounding CT scanning and to make policy recommendations concerning the use of and payments for CT scanning. Procedures which are currently being examined by the medical advisory committee include electromagnetic stimulation for bone repair and bone marrow transplant for leukemia.

RECOMMENDATIONS

While we will continue to make efforts such as these to assist plans, the associations have neither the capacity nor the expertise to do an optimal job of providing information on the cost effectiveness of medical technologies. Thus, in spite of our efforts, the local, cooperative, system of mechanisms which I have described is limited in insuring the appropriate application of technology by the lack of systematically derived information about the cost effectiveness of medical technologies. While decisions regarding the investment in and use of technology can best be made at the local level, it would be inefficient for each locality to attempt to derive the information needed to make these decisions. Clearly then, one of the keys to long-term health care cost containment is the establishment of a national technology assessment program. The general functions of this program would be to generate and disseminate knowledge on the efficacy and cost effectiveness of specific procedures, to investigate policy issues related to medical technology, and to investigate methodological questions related to technology assessment.

Given this general mission, the principle objective of the program should be to support the efforts discussed above, as well as the efforts of individual providers. In order for the program to achieve this objective, we feel that several issues should be addressed in the program's design:

(1) First, the impact of medical technology is broad. I have been focusing primarily on cost containment. However, medical technology usage also affects the quality of patients' lives; ethical and legal questions such as the right to die, provider liability, informed consent, and access to scarce technologies; resource allocation to competing medical and nonmedical needs; and the economic well-being of those whose income depends on the health care system. Thus, for the program to be effective, decisions must be made not only with an understanding of the needs of providers, planners, and payors, but also with an understanding of related economic, legal, and ethical questions.

We therefore feel that a technology assessment program should be guided by broad multidisciplinary direction. This past April, in testimony before the Subcommittee on Health and the Environment of the House Committee on Interstate and Foreign Commerce, (*11*) we proposed that the technology assessment program be

coordinated by an existing quasi-public organization having a broadly representative, multidisciplinary board. We specifically recommeded the Institute of Medicine. I would like to reiterate today our preference for this proposal. The Institute and the National Academy of Sciences are uniquely qualified to fulfill this role by their mission, make-up, past activities and disassociation from the operating responsibilities of the Federal Government in a way which we believe could not be approached by any Federal agency.

While we retain a strong preference for a quasi-public structure, we are also aware that the administration and Congress are moving toward the development of a technology assessment program within HEW. Given these developments, we are pleased that both H.R. 12584 and S. 2466 would provide a significant role for a multidisciplinary council made up of public and private representatives. We prefer the stronger role given to this council by S. 2466, which would require approval by the council for grants over $35,000 and which specifically designates the council as the advisory body on efficacy and technology policy.

Within the general structure envisioned by H.R. 12584 and S. 2466 we would go further to suggest that the council be responsible for functioning as a governing board for the agency. In addition, since the concept of a national technology assessment program is in its infancy, we would suggest that the council be responsible for annually reporting to the Congress on program progress and for recommending changes in the structure of funding levels of the program.

(2) The second issue to be addressed is the vast gap between the amount of assessment work which might be usefully performed and the limited capability to do this work. There are thousands of discrete medical technologies, each of which could require hundreds of thousands of dollars and several years to assess. Not only do we not have the monetary or manpower resources to assess even a fraction of these technologies, but the science of technology assessment is not highly developed.

Given our resources constraints, a mechanism for prioritizing technologies for assessments is necessary. We agree with H.R. 12584 and S. 2466 that risk and cost should be the first and second factors, respectively, in determining priorities. We also agree that prioritizing should be the responsibility of the mutlidisciplinary council.

In addition, we recommend that practical alternatives to costly clinical trials—such as expert consensus assessments—be conducted under the direction of the multidisciplinary council.

In light of our knowledge limitations, we agree with H.R. 12584, S. 2466 and the administration that a major function of the technology assessment programs should be to support studies designed to further develop the science of technology assessment.

Finally, we agree with H.R. 12584 that the program should be evaluated regularly by Congress to assess the state of development of technology assessment and the appropriateness of the structure and funding levels of the program. As I have already mentioned, we suggest that it be the responsibility of the multidisciplinary council to report to Congress.

(3) The final issue to be addressed in considering a technology assessment program is to insure that the program does not disrupt the cooperative efforts of local providers, planners, payors and others to contain costs. A technology assessment program should provide information to these parties to assist them in making decisions. It should not impose decisions in the forms of standards and guidelines. We feel that establishing the program within the Institute of Medicine would not only result in optimal productivity, but in addition would structurally clarify that the program's purpose is supportive.

If established within a Federal agency, the program should not have regulatory authority. This includes the generation of specific guidelines or standards for other Federal programs. However, a relationship should be established between the program and local cost containment efforts. For example, health planners may wish to limit the diffusion of a technology which is being assessed until after assessment results and to require that those providers using the technology provide needed data to the assessors. Thus, planners should be kept informed of technologies prioritized for assessment and of any data which the local health care system could provide to assist in assessing the technologies. Furthermore, since we feel that the ultimate objective of the program should be to provide information to local parties, we would suggest that the information dissemination function mandated in H.R. 12584 and S. 2466 be supported by specific funding authorizations.

In summary, we agree with legislation pending in Senate that now is the time to begin a formal national technology assessment program, rather than attempting to only study the issue and coordinate fragmented HEW activity. I have attempted to

stress our conviction that a technology assessment program should be designed around the cost containment efforts already in place. Such a program could multiply the effectiveness of these efforts and establish a basis for long-term cost containment in the health care system.

I appreciate the opportunity to appear before you today to present our views.

FOOTNOTES

(1) *Statement of the Blue Cross Association before the Council on Wage and Price Stability on Health Care Costs,* presented by Bernard Tresnowski, July 20, 1976, Chicago, Illinois.

(2) *Statement of the Blue Cross Association on Biomedical Research and Development,* presented to the Subcommittee on health and Scientific Research, Committee on Human Resources, United States Senate, by Howard Berman, April 1, 1977.

(3) *Statement of the Blue Cross Association on S.2410, Health Planning Amendments of 1978.* Presented to the Subcommittee on Health and Scientific Research, Committee on Human Resources, United States Senate, by Neil Hollander, February, 6, 1978.

(4) *A Statement on H.R. 10839, H.R. 11763 and H.R. 12166,* presented before the Subcommittee on Health and the Environment, Committee on Interstate and Foreign Commerce, U.S. House of Representatives, by Walter J. McNerney, April 17, 1978.

(5) U.S. Congress, Office of Technology Assessment, *Development of Medical Technology: Opportunities for Assessment,* August 1976.

(6) These Plans are Arizona; Colorado; Connecticut; Florida; Indiana; Kentucky; Maryland; Massachusetts; Michigan; Minnesota; Montana; New Hampshire-Vermont; Albany, Buffalo, New York City, Rochester, Syracuse, Utica, and Watertown, New York; Cincinnati, Ohio; Oklahoma; Rhode Island; Texas; Washington, D.C.; and Wisconsin.

(7) The Medical Necessity Program was begun with the assistance of the American College of Physicians, the American College of Radiology, and the American College of Surgeons. Other organizations participating in the program included the American Academy of Family Practice, the American Association of Medical Colleges, the American Hospital Association, the Blue Cross Association, and the Council of Medical Specialty Societies.

(8) NABSP Professional Affairs Division, *Computed Tomography, Impact on Health Care Costs,* November 1976.

(9) NABSP, *CAT Scanner: An Analysis of Technical Component Costs,* August 1977.

(10) Institute of Medicine, *Computed Tomographic Scanning, A Policy Statement,* National Academy of Sciences, Washington, D.C., April 1977.

(11) Op. Cit. 4.

Mr. SCHEUER. We really need an M.B.A. in this field. I, too, am an M.B.A., and it's long overdue that we apply the kind of hard-nosed business analysis to what we're getting for the taxpayer's dollar in the way of health outputs in technology.

Mr. Klein, why don't you chat with us. Your testimony will be printed in full in the record. Why don't you chat with us and then we probably will have some questions to ask you.

Mr. KLEIN. Thank you, Mr. Chairman and staff.

Mr. SCHEUER. You can address yourself to anything that has been said here today that has piqued your interest.

TESTIMONY OF DAVID KLEIN

Mr. KLEIN. Thank you. That's a license which would allow me to comment, I'm sure, on more than we would want to talk about today. I would like to focus on one particular item before getting into the body of the testimony which I have prepared and which I am ready to highlight here today. Of particular importance to us in reviewing the question of technology assessment is the nature the health insurance agreement which is made between an employer

and a Blue Cross and Blue Shield plan, or a commercial insurance organization, or a similar type of entity.

Underlying much of what has been suggested here today is a thought that the reimbursement mechanism, being basically an open-ended type of mechanism, is in large part the problem which needs to addressed. Concern has been stated about the fact that the preparedness of reimbursement is either through cost-based or rather rich charge-based mechanisms in which there is very little or no patient cost-sharing taking place. This concern has been noted by Drs. Russell and Cohen as one of the larger problems facing society today.

In constructing employee fringe benefit packages, employers, or if it's a negotiated-benefit situation, unions, are concerned about the satisfaction of the employee with the benefit. To satisfy their employees, they have taken the position of, "We want a paid-in-full, no-cost-sharing type of benefit." Thus, to address the open ended reimbursement mechanism problem, we must first change societal wants and desires.

Further evidence of this is seen in the political arena when we have tried to put forth programs which are less than full-service such as medicare. In these cases, the market has responded to the desire to supplement those programs with various types of complementary contracts.

The population that we serve collectively does not want—at least this is our perspective for 1978—us to give them less than a full-service coverage at this point in time. They are not willing to step up to the issues which I think Dr. Russell so well articulated earlier today.

With that, let me move into the highlights of my longer statement here.

In terms of the question of technology and the cost of health care, I'd like to concentrate on one aspect of this broad subject: What the Federal Government can do to support the efficient use of technology in the health care system.

In previous testimony, the Blue Cross and Blue Shield associations have consistently supported the establishment of a national program to promote, coordinate and conduct evaluations of efficacy and cost-effectiveness of medical technologies. We feel that such a program is needed in order to support the efforts of individual providers and other local parties to ensure the appropriate use of technology in the health care system. Therefore, any discussion of the design of a technology assessment program should begin with the consideration of the nature and limitation of these cross-containment efforts.

Two strategies can be used to foster the appropriate use of technology, we can either attempt to control the supply of technological capacity, or we can focus on the actual delivery of services.

Health planning is the major mechanism used to control the former. By insuring that health care facilities, services, and expensive equipment matches local needs, health planners can produce an environment which supports efficient technology uses.

Blue Cross and Blue Shield plans also play a role in controlling supply; first, by having the plan support local planning and tying provider payment to planning decisions; and, second, shifting re-

sources to more efficient health care services by altering health care benefit packages.

The other strategy to affect the use of technology is to ensure the actual delivery of services is appropriate. Utilization, we feel, whether performed within health care institutions or by Blue Cross/Blue Shield plans, PSRO's, or foundations for medical care, can be a tool to educate providers, and if necessary can be linked to payment sanctions.

Blue Cross and Blue Shield plans also support the appropriate delivery of services by experimenting with innovative benefits, such as preadmission testing, and second surgical opinion programs, and by not covering procedures which are outmoded, redundant, or experimental. In addit n, many plans are using payment methods which provide incentives for efficiency in the delivery of health services. In combination, these activities represent a broad evolutionary cooperative effort by local providers, payers, planners, government and other community members.

The key words here are "local and cooperative". Since health care needs vary among localities, health care services must be designed around an understanding of local conditions. Furthermore, none of the actors in the local delivery system can make significant progress without the cooperation of others.

As cooperation develops, each of the activities is hampered by the lack of authoritative basic data on the cost-effectiveness of specific medical technologies. For example, the determination of a community's need for either a general technology capacity, such as surgical beds, or a specific capacity, such as CT scanners, requires and understanding of both the extent of various illnesses and symptoms and of which technologies are effective in addressing them. Similar information is required by utilization review committees in hospitals and by Blue Shield and Blue Cross plans in establishing benefits and payment policies.

Blue Cross and Blue Shield associations have attempted to respond to information needs by a variety of activities. Our medical necessity program has resulted in the identification by the medical specialty organizations of 42 procedures for which plans are advised to require justification. Our national medical policy compendium is an ongoing tool to keep planners informed. In addition, our Medical Advisory Committee reviews in detail certain procedures with particular concern. Finally, we have commissioned or conducted indepth studies of some specific technologies such as CT scanning.

Dr. Wells. Would you support the recommendations made by Dr. Breslow as far as a commission to look into the CT scanning area?

Mr. Klein. In principle; yes.

However, it's quite clear that neither the associations, nor local providers, planners, and payers have the capacity or expertise to do the entire job of determining the cost-effectiveness of medical technology.

Clearly, one of the keys for long-term health care cost containment is the establishment of a national technology assessment program. Its principal objectives should be to support local efforts, such as those I have been discussing.

For the program to achieve this objective we feel that several issues should be addressed on the program's design. First, the program must address not only the needs of a variety of the local parties but also the economic, legal and ethical questions related to medical technology. We, therefore, feel the technology assessment program should have a broad, multidisciplinary direction. This past April we proposed that it be coordinated by existing quasi-public organizations having a broad, multidisciplinary board. We specifically recommended the Institute of Medicine. I would like to reiterate today our preference for this proposal.

The Institute of Medicine in the National Academy of Sciences is uniquely qualified to fulfill this role in a way be believe cannot be approached by any Federal agency. If a Federal agency is used, however, we recommended the multidisciplinary committee which would be established by H.R. 12584 and S. 2466 be responsible for functioning as the governing board of the agency.

The second issue to be addressed is the vast gap between the amount of assessment work which might be usefully performed and the limited capability to do this work. There are thousands of discrete medical technologies, each of which could require hundreds of thousands of dollars and several years to assess. Not only do we not have the monetary or manpower resources to assess even a fraction of these technologies, but the science of technology assessment itself is not highly developed.

Given our resource constraints, it would be necessary to establish priorities for assessment. This, we feel, should be the responsibility of the multidisciplinary committee. And the first two considerations should be risk and cost.

In addition, we suggest alternatives to costly clinical trials, such as expert consensus assessments, be considered.

In light of our knowledge limitations, a major function of the programs should be to support studies designed to further develop the science of technology assessment.

We also recommend the state of technology assessment be evaluated regularly by Congress to determine the appropriateness of the structure and funding levels of the programs.

Finally, we must ensure that the program does not disrupt the cooperative efforts of local providers, planners, payers, and others to contain cost.

Mr. SCHEUER. Would you say our present efforts, cooperative or otherwise, to contain cost are satisfactory?

Mr. KLEIN. No.

Mr. SCHEUER. Do you think the PSRO mechanism as it's working now is really doing the job?

Mr. KLEIN. By no means.

Mr. SCHEUER. Well, what's so holy then about what's going on now?

Why couldn't we devise something that would impose decisions and would have regulatory authority?

I think this paragraph is totally unsatisfactory as far as I'm concerned. You are just condemning us to live with the inadequate mechanisms that are there now. And if all this technology assessment entity can do is pass on information to the local decisionmakers, who don't have the guts to make the decisions that have to

be made now and are too timid and too full of their ownself to make the hard decisions, I think you are not presenting us with a very hopeful prospect.

I mean, you have heard all morning that a lot of this is sheer greed. You heard Dr. Breslow report that it took an agonizing amount of effort before the National Cancer Institute was able to get doctors—or to prohibit doctors from giving mammography, or whatever you call it, to women under 50, when there is absolutely no evidence of effectiveness, and there was considerable evidence of risk to the woman.

The medical profession still went blithely on its way cranking out those mammography tests when there was no evidence of efficacy but lots of evidence of income to doctors, hospitals, and the providers.

Now, would you want that to continue?

Mr. KLEIN. No, not at all.

The issue we're talking about here is one about change; how do we accomplish change most expeditiously and most effectively.

Mr. SCHEUER. Do you think that all we should do is provide information to local parties, and that the Federal Government should not be in a position to impose decisions on them or regulate the use of technology for which there is no efficacy proven whatsoever?

Mr. KLEIN. I would say in a situation of no efficacy, the actions there are clear.

Mr. SCHEUER. But they clearly continue. They clearly continue, and you heard one example that Dr. Breslow gave.

What is there in the history of the medical profession or as it is now that convinces you that they are capable on their own of making decisions relating to cost and efficacy?

Mr. KLEIN. I'm encouraged by the successes we have had in our medical necessity program, where a variety of medical specialty organizations have identified at this point 42 procedures which they feel are outmoded or redundant, and for which——

Mr. SCHEUER. How about mammography? Do you still pay for those tests for women under 50?

Mr. KLEIN. In terms of providing mammography exams for an asymptomatic population——

Mr. SCHEUER. Under 50.

Mr. KLEIN [continuing]. We generally do not pay for this.

Obviously, the payment policies vary around the country, but in general we would not pay for a test like that.

Mr. SCHEUER. That's encouraging.

I would have to part company with you on the penultimate paragraph of that page. But you are here to state a position, and that's the way our system works, you have the right to petition the Government.

Mr. KLEIN. Let me make one more comment along these lines.

Mr. SCHEUER. Certainly.

Mr. KLEIN. I think when the evidence is conclusive, a strong standard or guideline could be imposed; but the evidence often is not conclusive.

This is especially true when we get into the questions of——

Mr. SCHEUER. Well, Mr. Klein, What you're saying is that the technology assessing body should not engage in judgments beyond its capacity, or make irresponsible recommendations for guidelines; and I agree with you; I hope they won't; I expect that they won't. But, you know, that's a truism, it doesn't really mean anything, it doesn't add anything to the sum of——

Mr. KLEIN. Well, in terms of where we place the decisionmaking, do you want it to be at the local level where you can still have responsiveness, where when there is a legitimate difference of opinions they can be accommodated, or do you want to have a national uniform program? When you think about the performance of physicians in California versus Louisiana, and Texas versus New York, you find completely different mentalities.

Mr. SCHEUER. Yes, but you don't find completely different efficacies of mammography for an asymptomatic female client under the age of 50.

It seems to me the Federal Government is probably in a better position to say at the present time something like,

"We have looked at all the evidence in Texas, New York, California, and Vermont and since we find no efficacy for this particular client group the Federal Government is not going to pay for it. If you want to go out and pay for it on your own, go ahead, but the Federal Government won't do it."

There seems to be some king of myth that people know best at the local level; the local officials know best. Now, as far as I'm concerned that's absolute unadulterated nonsense. If that had been true, Mr. Klein, we would not have needed the Congress to tell the public school system of America that they ought to have a Head Start program.

Did you go to nursery school?

Mr. KLEIN. Yes.

Mr. SCHEUER. So did I, and so did my four children. There are a lot of middle-class people who sent their kids to kindergarten, prekindergarten, nursery school before that. It wasn't the best-kept secret of the age that kids can be oriented and helped to be made learning-ready, but it took the Federal Government to say, "Hey, let's give them a little education before first grade, particularly kids from disadvantaged homes."

Why weren't the local public school systems doing that? Answer me that.

Mr. KLEIN. I assume that there had to be a resource question at that point.

Mr. SCHEUER. Pure bunk, because all the educators will tell you that money invested early-on in the education system, especially prereading, that makes kids learning-ready, are the most cost-effective dollars you can put into the system.

I mean, "any fool knows that." But you show me the education system that went back and grabbed these disadvantaged kids and tried to help them or make them learning-ready at the age of two, three, or four.

I challenge the principle that all that much wisdom resides at the local level. I just don't think it's true.

Dr. WELLS. If I may interrupt.

I don't think you were suggesting that everything should be left at the local level. I think you were suggesting all decisionmaking

should not reside in this new Office of Health Technology, if I understood your point.

Mr. KLEIN. Right.

Mr. SCHEUER. How about elsewhere in the Federal Establishment in Washington?

Mr. KLEIN. I think the issue boils down to one of how do you force change; how do you get an acceptance for new positions from among providers—and that's where you're really starting.

These tests could still be rendered and then you have a patient out there with a $200 bill or a $300 bill for an uncovered service with a tremendous amount of dissatisfaction—it's a question of how do you get the providers to change their behaviors?

Mr. SCHEUER. Sometimes you have to wallop them on the head with a two-by-four to get their attention. You know the story of the man that was walloping the mule in Mexico, and some tourist says, "why are you torturing that poor beast." He said, "I'm not torturing it, I'm just trying to get his attention."

Mr. KLEIN. Let me try to summarize it one more time.

Mr. SCHEUER. Right now with doctors, nobody can say no, and they go merrily on their way making decisions that have no relationship to benefit. Somebody, on the basis of good evidence, has got to say no to some procedures or some reimbursement requests.

I'm not sure that where something is not clearly unefficacious that the Feds should say, as far as Federal dollars are concerned this is not going to be——

Mr. KLEIN. Yes. What do you do in a situation where it has some cost-effectiveness and it becomes a question of local judgment?

Let's look at the case of—I wish I were better versed in medical technology—but I have to imagine that there are some technologies for which it is a borderline case as to whether——

Mr. SCHEUER. We've had plenty of testimony here this morning that the real nitty-gritty issues are not where there is no efficacy, but where there is some efficacy, some minimal efficacy, sometimes relatively high cost.

Mr. KLEIN. Should we enforce standards for those types of services?

Mr. SCHEUER. Maybe some kinds of standards, and I don't propose that there shouldn't be local input, but certainly where there is no efficacy, I think the Federal Government has the right to say——

Mr. KLEIN. I would grant that, but I'm thinking more on the gray area of where there is some efficacy.

Mr. SCHEUER. In the form of standards and guidelines, I think the Feds have a right, yes, to provide some leadership that I presume would provide ample play for local decisionmaking.

I'm not saying the Feds should have the right, or even would want, to make decisions all over the lot; but to say that they should have no regulatory authority and should not impose decisions in the form of standards and guidelines, I feel that approach would be a very bleak one from the point of view of rational collective decisionmaking.

We thank you very, very much. We especially appreciate your patience. It is now 2:30 and we have been here for a good many hours.

We thank you for your participation.

The hearing will be suspended for now. The last day of hearings will be a week from Friday, October 6, at 10 a.m., in this room.

We thank you all for your patience.

[Whereupon, at 2:30 p.m., the subcommittee adjourned, to reconvene at 10 a.m. Friday, October 6, 1978.]

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TECHNOLOGY AND THE COST OF HEALTH CARE

FRIDAY, OCTOBER 6, 1978

HOUSE OF REPRESENTATIVES, COMMITTEE ON SCIENCE AND TECHNOLOGY, SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC PLANNING, ANALYSIS, AND COOPERATION, *Washington, D.C.*

The subcommittee met, pursuant to notice, at 10:15 a.m., in room 2318, Rayburn House Office Building, Hon. James H. Scheuer (chairman of the subcommittee) presiding.

Mr. SCHEUER. The subcommittee will be in order.

We will now commence the final day of hearings on technology and cost of health care.

We have a very distinguished array of witnesses and we are very pleased and grateful that with all of your busy and hectic schedules you made yourselves available.

We look forward to hearing from you.

I might say parenthetically we have been joined by Congressman Tony Beilenson, who is an active and thoughtful member of this committee and has played a major role in health care innovation in the California State Legislature, and we are happy to have him here.

In the first 2 days of hearings on this subject, we examined the role of technology in the rising costs of medical care. We heard from various witnesses that the inflationary impact of medical devices and advancing techniques owes much to the fact that insurance and Government subsidy makes it appear as free, the proverbial free lunch.

All of us, naturally, want the best in medical care for all Americans. But the potentially infinite demand for accelerating quality and intensity of service is reminding us, through soaring costs, that our resources are, after all, limited.

I am sure Members of Congress are going to need help in making some very hard decisions about where we stop providing health services, and whether we might not spend the money better, in different fashion. We have children who never get their immunization shots and we have elderly who need assistance in nutrition and housing, to name just a couple examples.

To get the most for the dollar in applying our limited resources, we want to be sure that medical devices and practices are maximally cost effective. And we want to be sure that the Government invests wisely in the development, evaluation, and use of health care technology.

Much of today's inquiry will focus on how this investment can best be managed by the Department of Health, Education, and Welfare. In particular, we will be concerned with prospective functions of the new Office of Health Technology or, if renamed by pending legislation, the Center for Health Care Technology.

We are pleased to have with us today a number of distinguished witnesses. A little later, after this panel, we will hear from Dr. Lashof and Dr. Banta how the Office of Technology Assessment can contribute to planning and management of health technologies.

Right now I want to welcome Dr. Julius Richmond, Assistant Secretary for Health, and Mr. Robert Derzon, Administrator of the Health Care Financing Administration.

I understand that Dr. Seymour Perry, Acting Director of the Office of Health Technology, and Dr. Mark Novitch, Deputy Associate Commissioner of the Food and Drug Administration have come to supplement Dr. Richmond's testimony, and we look forward to hearing from them. We hope you will spontaneously get right into the stormy matters and contribute.

Before we hear from Dr. Richmond, Congressman, would you like to make any comments?

Mr. BEILENSON. I don't think so, thank you, Mr. Chairman, except to say that I agree very strongly with what you said about choices having to be made, and I think we are going to have to make them quite soon.

Mr. SCHEUER. It's the conventional wisdom to say that every American is entitled to the very best in health care, and I think that is a crucial delusion. It isn't possible now, and it has not been possible in the past.

As I see it, even if our present 10 percent of GNP that goes into health services keeps rising to 11, 12, 14, 15 percent, at some point the American public is going to demand a cap on the portion of GNP going into health services because there are other competing demands, for education, jobs, environment, whatever.

Within the confines of the health care spectrum, I am sure that we are going to find we are not spending our moneys cost-effectively and so some very hard and agonizing decisions are overdue. And when these tough decisions come to me, I am going to give my proxy to Congressman Beilenson so he can make those tough decisions. [Laughter.]

I will tell his constituents out there how he has relieved me of these burdens. [Laughter.]

OK. Let's hear from Dr. Julius Richmond, and we hope the rest of the panel will join in and make individual contributions.

Dr. Richmond, we are delighted to have you here today.

Your statement—and this goes for everybody—your statement will be printed in full at this point in the record, so why don't you simply chat with us informally, hitting the highlights of our statement or presenting anything else that comes to mind, and then I am sure we will have some questions for you.

Dr. RICHMOND. Thank you Mr. Chairman.

[The prepared statement of Dr. Richmond follows:]

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DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

STATEMENT

BY

JULIUS B. RICHMOND, M.D.

ASSISTANT SECRETARY FOR HEALTH AND

SURGEON GENERAL

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC

PLANNING, ANALYSIS, AND COOPERATION

COMMITTEE ON SCIENCE AND TECHNOLOGY

HOUSE OF REPRESENTATIVES

OCTOBER 6, 1978

MR. CHAIRMAN AND MEMBERS OF THE SUBCOMMITTEE:

I am pleased to appear before you today to discuss the Department's efforts in the field of health technology assessment, transfer, and management. As you know, biomedical research and technological innovation have been responsible for profound improvements in the Nation's health. Some diseases have been eradicated; others can now be prevented; life itself has been extended; and much pain and suffering have been alleviated.

There is now emerging, however, a consensus:

- that many technologies have been widely adopted into medical practice without sufficient information about their health benefits, clinical risks, cost-effectiveness, and societal side effects;
- that the use of other technologies have persisted long after it was evident that they were of marginal utility, outmoded, or even harmful;
- and that still other well-validated innovations have been inordinately slow in finding their way to patient care.

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The consequences of such failures, which include spiraling health care costs and unnecessary procedures are now posing major dilemmas for patients, providers, planners, and third-party payers regarding the uses of existing and emerging technologies. The extent of technology's impact on health costs is difficult, if not impossible, to measure.

On the one hand, certain health technologies, such as immunizations and antibiotics, have produced tremendous savings in health care costs by preventing illnesses or their complications. Other technologies, such as automated billing systems, increase the efficiency of effective procedures. On the other hand, many technologies may increase the need for personnel and simply add to the "intensity" of care, without contributing significantly to outcomes. For example, certain diagnostic procedures, such as skull x-rays for head injuries, are conventionally done in many circumstances, but almost never influence treatment. The rapid dissemination and utilization of some new technologies, such as CAT scanners and coronary by-pass surgery, have required increases in costs without adequate evaluation of their efficacy or cost-effectiveness. Such increased "intensity of care" is clearly a major factor in the growth of health costs. The question that has to be answered is: which technology expenditures are justified and which merely underwrite the administration of ineffective or unneeded procedures?

Technology, with regard to the cost of treating one case of a disease or the total cost of a disease, appears to have different impacts depending on the particular disease under consideration. Those innovations that result in a substantial decrease in the incidence of disease itself appear to be cost-reducing while those that result in improving techniques of treatment of the disease seem to be cost-raising. For infective and parasitic diseases, diseases of the digestive and nervous system, the oral cavity, diseases of the skin and diseases of childbirth and pregnancy, expenditures have been reduced as a result of technology advances. And, as one would expect, the categories that result in increased costs include cancer, diseases of the circulatory system, cerebrovascular diseases, mental disorders, and endocrine and metabolic diseases. These individual disease costs while they must be factored into any cost-benefit analysis for health care costs surely render the issues even more complex when integrated into the continuum of technology assessment and technology transfer.

The assessment and transfer of technology are extremely complex. Assessment can include a large number of currently ongoing functions, such as clinical trials, consensus conferences,

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syntheses of research findings, and safety and efficacy studies of drugs and devices. Assessment also involves cost benefit and cost effectiveness studies, where the state of the art is still evolving. In addition, some technologies, such as neonatal intensive care, may raise important ethical issues and have a considerable impact on general societal values. There may be unanticipated side effects not recognized for a number of years, such as the suicide rate of renal dialysis patients.

Transfer of technology involves many users with different needs and different perspectives. Health Systems Agencies (HSAs) need information for planning at the local level, just as Professional Standards Review Organization (PSROs) need information for standard setting. Third-party payers require advice for payment decisions. Obviously the physician community-individual practitioners, medical schools and academic health science centers, and specialty societies-can benefit from results of technology assessment and incorporate these findings into the day-to-day delivery of care.

Office of Health Technology

In August 1977, the Department of Health, Education, and Welfare undertook a study to identify within the Department gaps in technology assessment and transfer and to make

recommendations for improving our assessment and transfer capability. Among other recommendations, the study proposed the creation of an Office of Health Technology to respond to the need for a stategy to link systemically the life cycle of technology development, evaluation, transfer, diffusion, utilization and phase-out. On July 17, 1978, the Office of Health Technology (OHT) within the Office of the Assistant Secretary for Health was created. This office will systematize and manage the diverse technology assessment activities which take place in the Public Health Service and other departmental agencies. It will assure that medical technologies are:

- more carefully scrutinized for their risks and benefits and
- assessed for cost benefits and societal impacts in order to promote:
  - -- more rapid introduction or phase-out of technologies;
  - -- more efficient organization and equitable distribution of technologies; and
  - -- more appropriate and effective use of technologies.

It is the aim of this Office to provide a balance between controlling costs of health care and over-controlling technological innovation at the expense of the quality of health care.

The Office of Health Technology has only recently become operational and as a result, has not yet been fully staffed. However, Dr. Seymour Perry, an Associate Director at the National Institutes of Health, has been appointed Acting Director. He has extensive experience in the field of health technology and has begun recruiting staff.

Along with its full-time staff, the Office of Health Technology will have an HEW advisory committee to assist the Office in policy development. The committee will be composed of individuals representing all the Public Health Service agencies, a representative from the Office of the Deputy Assistant Secretary for Health Policy, Research and Statistics, a representative from the Health Care Financing Administration, and other representatives as appropriate from the Office of the Secretary.

As mandated under legislation passed by both Houses of Congress, the Office of Health Technology will also have a national advisory committee to advise the Secretary concerning priorities for assessments to be undertaken, as well as to review grants and contracts

for such assessments. Its diverse membership will consist of individuals from outside government who have distinguished themselves in the fields of medicine, ethics, engineering, and biomedical and social science, such as practicing physicians, hospital administrators, economists, legal experts, third-party payers, ethicists, consumers and individuals representing the interests of the health care industry. Ex-officio members will include the Surgeon General, the Director of the National Institutes of Health (NIH), Director of the Center for Disease Control (CDC), Commissioner of the Food and Drug Administration (FDA), Administrator of the Health Care Financing Administration (HCFA), representatives of the National Professional Standards Review Advisory Council and National Health Planning Council, the Chief Medical Officer of the Veterans Administration, the Assistant Secretary of Defense for Health Affairs, Director of the Office of Science and Technology Policy, and other DHEW employees appointed by the Secretary.

For all of these health-oriented agencies, the Office of Health Technology should provide a forum for mutual information exchange on health technology activities,

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for airing individual agency perspectives on particular issues, for identifying critical needs and important opportunities in this area, and for seeking agreement on useful common approaches to problems and appropriate priorities. The OHT will act as a catalyst for policy development related to technology management, as well as functioning as a liaison to outside organizations, collaborating with other Federal agencies, and monitoring activities in the business and academic areas.

When fully staffed and operational, the Office will promptly select four to seven technologies that will receive a comprehensive assessment, including evaluation of cost and societal implications. Priorities for assessment will be set with full consideration of HCFA's needs in terms of reimbursement questions. In addition, the Office will explore and initiate activities with professional groups to facilitate transfer of information on technology.

In transfer activities, PSRO's represent a channel for getting information to the local medical community and can also use the information as appropriate in their own activities. Community hospitals can also serve as a central point in a communication network, passing on information through staff meetings and other means.

Health Care Financing

One of OHT's most urgent responsibilities is to provide assessment results to the Health Care Financing Administration (HCFA) for use in reimbursement decisions under the Medicare and Medicaid programs. As you may know, when HCFA was established, its Administrator and the Assistant Secretary for Health agreed that the Public Health Service would provide ongoing techical advice to queries from HCFA on whether specific medical services should be covered under Medicare/Medicaid.

HCFA, in administering the Medicare program, is responsible for determining what services are reasonable and necessary for diagnosis and treatment of illness or injury and are therefore reimbursable. HCFA is also responsible for advising the various States of these determinations for use in making payment decisions under Medicaid. As medical science advances at a rapidly growing rate, questions are raised about the safety, efficacy and appropriateness of the newly developed tests and treatments as well as the relative efficacy of existing technologies which may not have been assessed.

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Under Medicare questions arise in several ways, for example, when a claim for the service is first submitted for reimbursement; when the professional community begins to question the continued use of a procedure in view of recent advances; when manufacturers ask about Medicare coverage before an item is marketed; or when medical societies and others raise questions. When the question is the result of a request for reimbursement, timely response is necessary so that (1) the provider will know if Medicare will pay for the service or device, and (2) public and physician goodwill will be maintained by prompt payment or at least notification of denial so that other arrangements can be made. We expect that OHT, through a set of procedures initially developed by the PHS Office of Health Practice Assessment (OHPA) and now in the process of being put into place, will be able to expedite responses to HCFA's queries.

While all coverage questions require a timely response, not all require the same level of effort to answer. These determinations do not require a full assessment of the ultimate value of a particular procedure or device, but an analysis of the state of the art today. As part of its determination, OHT could appropriately identify

the additional information needed in an area and take the lead in developing it or assuring its development. Coverage questions, therefore, will need to be reconsidered as more information is developed after the initial response has been given.

Public Health Service

As you know, a number of Public Health Service (PHS) components have been engaged in different aspects of technology assessment and transfer.

National Institutes of Health

Relevant to technology assessment concerns, the National Institutes of Health (NIH) has already taken several significant new steps to address problems from a biomedical research perspective. An Associate Director for Medical Applications of Research was appointed in January of this year to provide a point for technical staff coordination across NIH components and to assist the Institutes in their assessments of health technologies in terms of safety, efficacy, and effectiveness, and with concern also for ethical and cost considerations. To date, "consensus development" conferences have included assessments of breast cancer screening, mass screening for colo-rectal cancer, dental implants, the educational

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needs of physicians and the public regarding asbestos exposure, and preliminary meetings on the indications for tonsillectomies and adenoidectomies. The recommendations developed at these conferences have been disseminated to the practicing community, HCFA, and the public through various channels.

I would like to include for the record a schedule of the NIH "consensus conferences" through which selected technologies are evaluated for safety and efficacy (Attachment 1)

The Office of Medical Applications of Research (OMAR) at NIH will provide:

- technical input to the Office of Health Technology regarding the identification of priorities;
- recommendations on the readiness of a given technology for assessment; and
- technical information on clinical safety and efficacy for use by the Office of Health Technology in its broader responsibility for comprehensive technology assessment.

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The mission of the Food and Drug Administration (FDA) involves critical responsibilities that pertain to the assessment of certain medical technologies, specifically drugs and biological products, medical devices, and radiation sources and techniques, including electronic products and nuclear medicine, employed in health care. Federal law requires FDA to pass judgment on the safety and effectiveness of these medical technologies; indeed without FDA approval, the products subject to its jurisdiction cannot lawfully be marketed in interstate commerce. FDA's activities, therefore, will contribute immeasurably and continually to the efforts of OHT.

It is important to note in this connection that the ability of FDA to gather and act on information pertaining to the use of approved drugs will be greatly expanded by passage of the Drug Regulation Reform Act. That legislation, in addition to effecting fundamental reform in the present cumbersome system for pre-market review and approval of new drugs, will also enable FDA to speed the introduction of highly significant "breakthrough" drugs, to monitor the clinical experience obtained with newly approved drugs, and to aid the medical profession in determining that a drug may be of important value in patient care in ways not originally anticipated or recognized either by its developers or by FDA.

These issues, as I am sure you appreciate, involve sometimes agonizingly complex assessments of risk versus benefit in resolving problems in which health, social, and ethical parameters may be and often are in conflict with economic issues. Earlier this year, the FDA conducted a symposium on risk/benefit decisions and the public health. This symposium and others on developing scientific technologies serve to generate careful examination of complex health technology and health policy issues.

Of a more immediately practical nature, the FDA's Bureau of Radiological Health has as one of its primary tasks the monitoring of various radiation exposures including medical radiation exposure, assessment of public health risks, and implementation of actions to reduce unnecessary radiation exposure. Equipment performance standards, medical radiation use recommendations, compliance programs to reduce radiation exposure, and symposia and conferences to reduce unnecessary medical radiation exposures are used to achieve improved patient health care through the assessment of medical radiation technology and the dissemination of information to health care professionals and patients. This assessment, of course,

can have a clear impact on health care costs and risks if reduced use of x-rays and other radiation is the result. I would like to submit for the record a listing of the recent radiation protection activities (Attachment 2).

When the Office of Health Technology is fully operational, the Food and Drug Administration will provide:

-- information on the safety and effectiveness of drugs, biologicals, medical devices, and diagnostic products approved for use, and
-- recommendations and priorities for an assessment of medical technologies.

National Center for Health Services Research

The National Center for Health Services Research (NCHSR) has also been engaged in technology assessment and transfer activities related to hospital management, information, billing systems and the use of computer and communications technology for the delivery of services in rural areas. Testimony on specific NCHSR activities was presented to your committee in May. NCHSR also will participate actively in the design and implementation of cost benefit and cost effectiveness studies and will participate in ethical and social effects studies.

National Center for Health Statistics

The National Center for Health Statistics (NCHS) maintains several statistical systems that produce data of potentially great value to the Office of Health Technology, such as information regarding the prevalence of medical conditions for which a given technology might be indicated, as well as the burden these conditions impose on our population. Statistical data on medical care expenditures and technology transfer surveys which provide a basis for tracking the rate and extent of diffusion of new practices should also serve to aid the OHT in developing priorities for the study of medical technologies.

Health Resources Administration

The Health Resources Administration (HRA), in its support of health planning efforts at the local and State level, has major responsibilities for the transfer of information on technology. National guideline standards issued by HRA address the appropriate supply, distribution, and organization of health resources. Health Systems Agencies and the State Health Planning and Development Agencies at the local level are expected to review and approve the need for new institutional health services and equipment and will by verifying the appropriateness of existing health services. The

National Council for Health Planning makes recommendations to the Secretary with respect to the national guidelines and national health goals and is expected to evaluate the implications of new medical technology on the organization, delivery and distribution of health services.

Center for Disease Control

The Center for Disease Control (CDC) has been engaged in technology assessment related to its mission of disease prevention and occupational health. Its risk-benefit studies of smallpox vaccine demonstrated that this vaccine should no longer be routinely used in the United States thus saving lives and hundreds of thousands of dollars. Cost benefit studies at CDC have shown the value of measles and rubella immunization programs and given new perspective to chronic renal disease management. The risks of various family planning technigues have been identified and quantified by CDC surveillance activities. In the occupational health area, the National Institute for Occupational Safety and Health has an initiative underway to assess technology in high-risk, small business-oriented industries to determine the exposure risks and the benefits of improving the existing technology.

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Summary

In summary then, HEW has had major responsibility for technology assessment and transfer as a creator, assessor and user. Until recently these activities were not well coordinated. The Office of Health Technology was established to manage technology, to identify priorities for the agencies and to coordinate and integrate activities that range from the initial development of promising technologies to transfer of knowledge to users such as the HSAs, third-party payers and practitioners. I would like to submit for the record a diagram outlining the steps in the process of technology management (Attachment 3) which will serve as a guide for OHT activities.

Societal attitudes toward "progress" pressure physicians and patients alike to embrace new medical technologies before their value has been established. Definitive information on the value of a technology may be a long process requiring longitudinal data on outcomes. Yet sound technological analyses can affect the attitudes of health professionals and patients and provide a means for encouraging technological innovation and application while providing a balance between controlling the costs of health care and improving its effectiveness. We believe

that the Office of Health Technology will serve to meet these needs. However, many of the issues in health technology assessment and transfer relate to societal decisions to distribute resources. If a new technology is developed yet not transferred or is available in limited amounts, who gets it and who decides? If a new technology is costly yet constitutes only a marginal improvement on a less costly technology, should it be introduced and should Federal reimbursement programs pay for the costly procedure? These are complex issues that require extensive public dialogue.

The Congress, the Administration, and the Department have recognized the need for a better means to assess and management technology. These hearings should make an important contribution to the development of strategies in this critical policy area. We must all share insights through wide public debate as we attempt to bring some order and precision to technology evaluation and management.

Mr. Chairman, we will be happy to answer any questions you or the members of the Subcommittee may have.

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Attachment 1

Seymour Perry, M.D.
August 30, 1978

Notional Institutes of Health

STATUS REPORT - CONSENSUS DEVELOPMENT ACTIVITIES

Dates	Institutes/OD	Titles	Format	Place
Sept. 14-16, 1977	NCI	Consensus Development Meeting on Breast Cancer Screening	Conference	NIH
May 22, 1978	NCI	Educational Needs of Physicians and Public Regarding Asbestos Exposure	Conference	Holiday Inn, Bethesda, MD
June 7-9, 1978	NIEHS	International Cadmium Conference	Conference	NIH (Wilson Hall)
June 12-14, 1978	NIDR	Dental Implants: Benefit and Risk	International Conference	Harvard School of Dental Medicine Boston, MA
June 19-20, 1978	NIH Nutrition Coordinating Committee	The Biomedical and Behavioral Basis of Clinical Nutrition: A Projection for the 1980s	Panels and formal presentations	NIH (Masur Auditorium)
		Final Meeting for Consensus Development to be held Sept. 11, 1978	Panel	NIH
June 26-28, 1978	NCI	Mass Screening for Colo-Rectal Cancer	International Conference	Holiday Inn, Bethesda, MD
July 10-11, 1978	NIA	Treatable Brain Diseases in the Elderly	Panel	NIH
July 20, 1978	NINCDS	Indications for Tonsillectomy and Adenoidectomy - Phase 1-Meeting	Panel	NIH
Sept. 5, 1978	NIH Nutrition Coordinating Committee	Total Parenteral Nutrition (planning meeting)	Planning Group	NIH
Sept. 14, 1978	NIAID	Availability of Insect Sting Kits to Non-Physicians	Panel	NIH (Wilson Hall)

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Dates	Institutes/OD	Title	Format	Place
Sept. 18-20, 1978	NCI	Mass Screening for Lung Cancer	Conference	Sheraton International Boston, VA
Sept. 23, 1978	NICHD	Antenatal Diagnosis-Planning Meeting	Panel	San Francisco, CA
Sept. 25-26, 1978	NIEHS	Standard for Laboratory Use of Toxic Substances Posing a Potential Risk	Conference	Masur Auditorium, NIH
Oct. 12-13, 1978	NHLBI	Early Hospital Discharge of Patients with Uncomplicated Myocardial Infarction	Panel	NIH (Building 31, Conference Room 8)
Oct. 20, 1978	NIA	Post-Menopausal Estrogen Treatment-Planning Meeting	Panel	NIH
Oct. 20-21, 1978	NCI	T-cell lymphomas and mycosis fungoides	Conference	Washington, D.C.
Nov. 10-11, 1978	NIGMS	Supportive Therapy in Burn Care	Workshop	Masur Auditorium, NIH
Dec. 4-5, 1978	NIAMDD	Surgical Treatment of Morbid Obesity	Conference	Wilson Hall, NIH
1978 (Date to be determined)	NCI	Rehabilitation for Cancer Patients	Conference	Place to be determined
1978 (Date to be determined)	NIEHS	Workshop on Percutaneous Toxicology	Workshop	Place to be determined
Spring, 1979	DRS (BEIR)	The Use of Microprocessor-based, 'Intelligent,' Machines in Patient Care	Conference	NIH
		Preliminary Workshop #1 - 5/30-6/1/78		NIH (Bg. 13/Rm 3W54)
		Workshop #2 - 6/19-6/21/78		(Bg. 13/Rm 3W54)
		Workshop #3 - 7/20-7/21/78		(Bg. 31/Rm 4)
		Workshop #4 - 8/23-8/25/78		(Bg. 31/Rm 4)

Dates	Institutes/OD	Titles	Format	Place
Nov. 12, 1978	NHLBI	Prevention of Venous Thrombosis and Pulmonary Embolism-Planning Meeting	Panel	Place to be det.
Feb. 15, 16, 1979	Interagency Committee on New Therapies for Pain and Discomfort	Pain and Its Relief	2 days; Panels and formal presentations	Natcher Auditorium, NIH
1979 (Date to be determined)	IOM/NCI-NIA	Last Days of Care	Conference	Place to be det.
1979 (Date to be determined)	NCI (DCCR)	Health Education Priorities for Cancer Control	Workshop	Place to be det.
1979 (Date to be determined)	NHLBI	Use of Extracorporeal Membrane Oxygenator (ECMO) in the Treatment of Adult Respiratory Failure	Public Meeting	Place to be det.
1979 (Date to be determined)	NEI	Photocoagulation Therapy for Diabetic Retinopathy	Panel	Place to be det.
1979 (Date to be determined)	NIEHS	Validation of Short-Term Tests as Predictors of Carcinogenic and Mutagenic Activity	Conference	Place to be det.

Attachment 2

FOOD AND DRUG ADMINISTRATION/BUREAU OF RADIOLOGICAL HEALTH

Radiation Protection Activities

(For inclusion in Dr. Richmond's health technology transfer testimony.)

Overall Mission: Monitoring radiation exposure of population from medical and consumer products; assessing public health risks; conducting action programs to reduce unnecessary exposure - authorized by P.L. 90-602, The Radiation Control for Health and Safety Act.

I. REGULATORY EQUIPMENT PERFORMANCE STANDARDS

Goal: To eliminate unnecessary radiation exposure by means of design and manufacturing safeguards.

1. Medical Products

- Diagnostic x-ray equipment - August 1, 1974 (effective date)
- Ultrasound therapy equipment - February 17, 1979 (effective date)
- Microwave diathermy equipment - proposed

II. VOLUNTARY MEDICAL RADIATION (USE) RECOMMENDATIONS

Goal: To provide Federal guidance to the medical community regarding prudent use of medical radiation.

1. Examples of existing and proposed FDA recommendations and/or guidance

- Mammography screening
- Mass chest x-ray screening
- X rays during pregnancy
- Quality assurance in diagnostic radiation facilities
- X-ray examination exposure limits
- National standards for medical radiation technologists
- Skull x rays following trauma
- Radiation treatment of benign diseases

III. ACTION PROGRAMS

Goal: To reduce population exposure to radiation via surveillance over x-ray usage trends and implementation of appropriate remedial programs.

1. Breast Exposure: Nationwide Trends ("BENT"): is a mammography exposure reduction and quality assurance program conducted by 44 State and local radiation control agencies (up to 50% x-ray dose reduction).

2. Dental Exposure: Normalization Technique ("DENT"): is a dental x-ray exposure reduction and quality assurance program conducted by 36 State and municipal radiation control agencies (40 % average dose savings).

3. Nationwide Evaluation of X-Ray Trends ("NEXT"): is a system for monitoring and measuring the effectiveness of State and Federal regulatory activities directed at reducing x-ray exposure.

4. Radiological Health Sciences Learning Laboratory: is an integrated learning system presently in three-fourths of all U.S. medical schools; teaches patient selection, x-ray physics, and x-ray interpretation (diagnosis).

IV. MAJOR RADIATION PROTECTION CONFERENCES - 1977-78

1. National Conference on Referral Criteria for X-Ray Examinations (October 25-27, 1978).

   Purpose: To outline the dual problems of unnecessary radiation exposure and unnecessary health costs resulting from overutilization of x rays; develop strategy for developing x-ray referral criteria for health professionals.

2. Symposium on Biological Effects and Characterization of Ultrasound Sources - June 2-3, 1977.

3. National Conference on Educational Programs in Nuclear Medicine Technology - May 10-12, 1978.

   Purpose: To explore the present overall national educational program effort for nuclear medicine technologists and to develop suggestions and recommendations for strengthening this effort.

4. Symposium on Real-Time Radiological Imaging: Medical and Industrial Applications - May 8-10, 1978.

   Purpose: To acquaint members of the industrial and medical communities with the state-of-the-art technology and to provide an opportunity for cross-fertilization of ideas and opinions.

5. Tenth Annual National Conference on Radiation Control - April 30 - May 4, 1978.

   Purpose: To provide for an exchange of information between State and Federal agencies responsible for radiation control.

6. Second Image Receptor Conference: Radiographic Film Processing - March 31 - April 2, 1977.

   Purpose: To discuss and identify problems/solutions associated with film processing in diagnostic radiology.

7. Symposium on Biological Effects and Measurements of RF/Microwaves Proceedings - February 16-18, 1977

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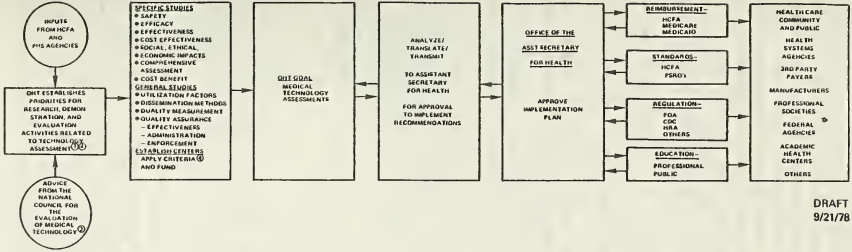
A PROCESS FOR OHEW HEALTH TECHNOLOGY DEVELOPMENT



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FOOTNOTES –

(1) OHT FUNCTIONS
REFERENCE FUNCTIONAL STATEMENT DATED 7/17/78

- IDENTIFY DEFICIENCIES IN OHEW'S HEALTH TECHNOLOGY POLICY AND PROPOSE IMPROVEMENTS
- COORDINATE DEVELOPMENT OF PROCESSES FOR COLLABORATION BETWEEN OHEW AND OTHER FEDERAL AGENCIES REGARDING TECHNOLOGY MANAGEMENT ACTIVITIES
- MANAGE THE DEPARTMENT'S PROCESS FOR
  - SELECTING HIGH PRIORITY TECHNOLOGIES
  - OVERSEEING CONVOCATION OF PROFESSIONAL JUDGMENT
  - PREPARING INFORMATION DOCUMENTS FOR THE SECRETARY RELATING SELECTED TECHNOLOGY FINDINGS TO REIMBURSEMENT, REGULATION, AND OTHER DEPARTMENTAL INITIATIVES
- CONDUCT OR OVERSEE THE CONDUCT OF FORMAL EVALUATIONS OF COMPONENTS OF THE DEPARTMENT'S TECHNOLOGY MANAGEMENT SYSTEMS
- ANALYZE OR MONITOR ANALYSIS OF STUDIES TO DETERMINE FEASIBILITY AND COST EFFECTIVENESS OF A COMPREHENSIVE SYSTEM FOR MONITORING AND SCREENING HEALTH TECHNOLOGIES
- DIRECT AND/OR CONDUCT TESTS OF THE APPLICATION OF COMPREHENSIVE TECHNOLOGY ASSESSMENTS INCLUDING EVALUATION OF ETHICAL, ECONOMIC AND SOCIAL CONSEQUENCES TO EFFECTIVE TECHNOLOGY MANAGEMENT
- DIRECT AND/OR CONDUCT PILOT DEMONSTRATION PROJECTS TO TEST THE APPLICATION OF A TECHNOLOGY MANAGEMENT STRATEGY IN A LIMITED NUMBER OF HIGH PRIORITY TECHNOLOGIES
- ESTABLISH LIAISON WITH EXTRADEPARTMENTAL PARTIES AND AGENCIES WITH WHICH TO LINK OUR TECHNOLOGY ACTIVITIES IN ORDER TO DEVELOP COLLABORATIVE WORKING RELATIONSHIPS TO FACILITATE JOINT ACTION
- PROPOSE LINKAGES BETWEEN DEPARTMENTAL AGENCIES TO PROMOTE INCREASED COORDINATION ON TECHNOLOGY ISSUES AND ON SPECIFIC TECHNOLOGIES
- OASHT SERVES AS PRINCIPAL ADVISOR TO ASH ON HEALTH TECHNOLOGY MATTERS
  - REPORTS ON OHEW ACTIVITIES
  - SUGGESTS CHANGES
  - PROVIDES TECHNOLOGY ASSESSMENT RESULTS TO OHEW ORGANIZATIONS ON REIMBURSABLE SERVICES AND TRANSFER OF INFORMATION

(3) PRIORITIZATION CRITERIA
- ACTUAL OR POTENTIAL
  - RISKS
  - BENEFITS
- VOLUME
  - PER CASE
  - IN AGGREGATE
- RATE OF UTILIZATION
- STAGE OF DEVELOPMENT

(2) NCEMT COMPOSITION –

18 MEMBERS APPOINTED BY THE SECRETARY OHEW:
6 MEDICAL AND SCIENTIFIC (INCLUDING 3 PRACTICING PHYSICIANS AND 2 PRACTICING HOSPITAL ADMINISTRATORS
2 ECONOMICS
2 LAW
4 OTHER PUBLIC

EX OFFICIO –
SURGEON GENERAL
DIRECTOR NIH
CHIEF MEDICAL OFFICER VA
CHAIRMAN NATIONAL PSRC
CHAIRMAN NATIONAL HEALTH PLANNING COUNCIL
ASSISTANT SECRETARY OF DEFENSE FOR HEALTH AFFAIRS
3 OTHER EMPLOYEES OF OHEW APPOINTED BY THE SECRETARY

(4) CRITERIA
- FULL TIME EXPERT DIRECTOR
- MULTIDISCIPLINARY STAFF
- ESTABLISHED ACADEMIC OR RESEARCH INSTITUTION WITH APPROPRIATE RESOURCES

TESTIMONY OF JULIUS B. RICHMOND, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; SEYMOUR PERRY, M.D., ACTING DIRECTOR, OFFICE OF HEALTH TECHNOLOGY, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; ROBERT A. DERZON, ADMINISTRATOR, HEALTH CARE FINANCING ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; MARK NOVITCH, M.D., ACTING ASSOCIATE COMMISSIONER FOR HEALTH AFFAIRS, FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE; DR. CAROL EMMOTT, SPECIAL ASSISTANT, OFFICE OF HEALTH LEGISLATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Dr. RICHMOND. My associates and I are pleased to be with you today to share with you and other members of your subcommittee the progress which we have made in developing a technology assessment and management capacity in HEW.

I would also like to introduce, in addition to those accompanying me whom you already introduced, Dr. Carol Emmott, Special Assistant in the Office of Health Legislation.

We are gratified, Mr. Chairman, by your interest in this very important subject, and I know we will benefit greatly from these proceedings.

I cannot help but interject that it's always a pleasure to appear before you, because of what I have observed to be your deep commitment not only to the health, but also to the education and to the welfare of the American people. As a pediatrician I would again like to take note of the many contributions you have made to child health.

Mr. SCHEUER. Why do you let your voice fall so low when you get to this point in your testimony? [Laughter.]

Dr. RICHMOND. I hope it's recorded.

Mr. SCHEUER. That's much better.

Dr. RICHMOND. Mr. Chairman, as you suggested, my more comprehensive remarks will be submitted for the record. I would like to take just a very few minutes to make some introductory comments and address what we view as the very complex problem in our society involved in the study and management of technology in the field of health.

All of us, of course, have benefited in some way from the advances in technology as you have already noted. Our National Center for Health Statistics tells us that our health indicators reveal that the American people are the healthiest, by almost any criterion, that they have been in the history of this Nation.

We view this technology problem in a very broad sense, as including not just the hardware, but specific preventive, diagnostic and therapeutic approaches to health care, from automated electrocardiograms to vaccines.

The explosion of medical knowledge in this century and particularly since World War II has had a profound effect on the quality and the length of life of our people. Yet we all pay in both dollars and health risks for the overuse and inappropriate use of medical technologies, which you have already commented on.

What we hope to do through the establishment of the Office of Health Technology or through a center for health technology and in accordance with legislative mandate in the Department, is to provide some perspective and rationality to the process through which medical and health practices evolve.

Presently, old and ineffective therapies are perhaps too slowly replaced by innovative, more efficacious ones and unproven and more costly modes of therapy often find their way into use with insufficient evaluation. It is the correction of these problems we hope to effect in part by the systemmatic approach envisioned for the Office of Health Technology.

We have been making progress toward establishing the Office. We have undertaken the first steps required to get it up and running, and we anticipate operating at full capacity very shortly.

Dr. Seymour Perry, who is with us, holds the title of Acting Director, and Acting Deputy Assistant Secretary to me, and he has begun to recruit staff.

An interagency committee has been established to assure that the Office has the broad participation of all of the related departmental components in policy and priority setting.

Agreements have been reached with Dr. Derzon and the Health Care Financing Administration regarding procedures for assuring the best use of the Office's capacities in getting to the complex coverage issues facing the Health Care Financing Administration.

We expect close collaboration with the Food and Drug Administration which will provide valuable lessons for our activities through its long standing mandate to evaluate the safety and efficacy of drugs and medical devices.

The Bureau of Health Planning in the Health Resources Administration is another departmental component we expect will collaborate closely with the Office of Health Technology. The planning process, as you know, is one of our major points of leverage on the shape of health practice. We expect that health planners will be directly aided in their difficult task by the work of this Office.

The National Center for Health Services Research and the National Center for Health Statistics will be closely linked in order to make maximal use of the special analytic capabilities of each of these centers. In addition, the Center for Disease Control will be involved as will other components such as the Bureau of Health Manpower.

The recent passage of H.R. 12584 will help assure that the technology activities we have initiated administratively will have a statutory base and will be provided additional resources. Meeting this mandate and expanding the initial scope of the office activities will clearly require some additional start-up time.

One requirement of the House and Senate bills is, we believe critical to the success of the Office. The creation of an advisory committee or council to provide advice from a broad group of private sector interests with special expertise in this complex policy area is essential to building linkages with the diverse actors in the system of technology development.

The appointment of this advisory board will be among our highest priorities.

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The charge to the Office of Health Technology ultimately requires introducing some rationality to the interaction of almost every component of the health care system.

Rather than attempt to be comprehensive in these remarks we can be most responsive, as you suggested, by spending the major amount of time in responding to questions.

Mr. SCHEUER. Dr. Richmond, one question that I want to ask is about the use of this advisory committee.

How would the people be selected and what would the criteria be and how would their concerns and perceptions be cranked into the process in a way that is meaningful?

We had testimony a few months ago in this committee on the operations of the advisory committee on rape and violence in the NIMH and it was a real disaster. They were not consulted. When they drew up the reports, the head of the Rape Center sat on the advisory committee as the secretary and redrafted and edited and censored the report before sending it to the Secretary.

It was monstrous. I could not believe this could happen in America. I don't just say that demagogically; it was a total perversion of the Congressional perception of what advisory committees are all about, and what their useful potential is, and we never really had a very satisfactory answer. I think we wrote some letters.

Dr. WELLS. We have amended the legislation now to require greater independence on the part of the advisory committee so that the reports will be made available directly to Secretary Califano.

Mr. SCHEUER. But the point is, we should not have to sit here closing loopholes as the concept of the advisory committee is egregiously misused. We should not be in the business of having to have hearings on the shameful abuse of that concept and then having to close loopholes.

We should not have to do that here. I didn't mean to get off on a long soliloquy on this matter, but our experience has raised a red flag on advisory committees, so we look for some assurances from you on that subject.

Please proceed.

Dr. RICHMOND. I can assure you, Mr. Chairman, that we do take the matter of an advisory committee for this program very seriously. Indeed, I would go so far as to say we cannot really do the job without getting the broad kind of representation on an advisory committee and getting their input. I would add that the Secretary is very committed to an open process.

I think you will recall in relationship to the influenza vaccine proceedings recently, that broad extramural committee advice was sought. The process was very well protected so that we would get the widest kind of input. Just earlier this week we have had a conference with people from all around the country to help us in defining a research policy for the next 5 years, what kinds of research support we will need at the National Institutes of Health and in our other agencies.

I mention this because, while there may have been some errors in the past, we are in the process of opening up participation rather than trying to preclude it, or in any way to constrain it.

On this committee, Mr. Chairman, we would anticipate having from the extramural community participation by scientists from

around the country who are knowledgeable in this field and who have some expertise. We would solicit, the widest kind of input in terms of candidates. We would certainly want representation from the practitioner community, not only physicians, but all health practitioners.

I cannot say we will have all of the health disciplines represented, but we would want to get appropriate representation, and where they cannot all be represented, to have that advisory group be provided consultation. We would certainly want to have some representation from industry, which has a good deal of expertise in this whole area, and from the public more broadly.

We certainly should have citizen representation. I should, of course, include people from the fields of sociology and other social sciences, and also people who are——

Mr. SCHEUER. Economics, I would hope you would have at least one health economist on that advisory committee.

Dr. RICHMOND. Yes, indeed.

Mr. SCHEUER. There is so much involved in cost benefit analysis of high technology and the associated use of tertiary hospital beds, as an alternative to low technology out-patient ambulatory services.

True, much of that is a matter of sociology and, of course, it's a matter of health, but it's also a matter of economics, and I would hope there would be a health economist on there.

Dr. RICHMOND. Yes, certainly.

Mr. SCHEUER. My basic education in health economics came from a book called, "Who Shall Live" by Victor Fuchs, and it really was a seminal experience for me. It changed my whole perception of how you analyze health care systems.

Dr. RICHMOND. I would only reenforce your comment.

Certainly cost/benefit analyses in this field are only in their infancy and what we really need is a larger corps of economists who will enhance the development of in this field.

But I mention public participation as well as people who have some specific background in ethics, because certainly where choices need to be made we want representation from the public. We will administer the program, but they will be essentially the governing board for the program.

Mr. SCHEUER. And help construct policy.

Dr. RICHMOND. Right.

Mr. SCHEUER. Very good.

Dr. RICHMOND. I have some other very brief comments, Mr. Chairman.

I did comment earlier on the complexity of the task. It's as broad and deep as the entire field of medicine. Health, as you have already noted, ranges from basic research through applied research and development, clinical investigation, clinical trials and field tests, technical consensus development, dissemination of information to professionals and to the public at large, and the matter of how these technologies are applied in practice and even perhaps just as significantly how they may be withdrawn from practice when they become obsolete or ineffective.

When we add to this the matter of cost/benefit analysis and the infant state of that art, I think we have some idea of the complexity.

This week we have had a dramatic example of two of these instances. Secretary Califano had a press conference on Wednesday, and he commented on two technologies. One [was] the matter of diethylstilbesterol and its use presumably for the prevention of miscarriage in pregnancy, something that was introduced more than 20 years ago. What the Secretary was announcing was that we should be very cautious about the use of that drug. Its hazards have appeared some 20 years later and have been recognized very clearly. This represents a clear example of something which should largely be withdrawn from application.

In the same conference, he announced our decision in the Department to move forward with a program for the elimination of measles within the United States to the extent that it is possible since it isn't completely controlled throughout the world.

Our immunization initiative has now had sufficient impact so that the numbers of cases of measles being reported are sufficiently low that we can now move toward a containment strategy and by 1982, which is the target we are setting, we hope we can virtually eliminate measles.

For one who has been a pediatric practitioner like myself, I can understand the tremendous importance of the gains that we have made.

Mr. SCHEUER. Are you suggesting that it's your goal as a pediatrician to provide preventive services to the entire target group at risk by 1982?

Dr. RICHMOND. That's correct.

Mr. SCHEUER. Do you think that is sound?

Dr. RICHMOND. Yes, we do.

Mr. SCHEUER. Can I ask you why you have not provided a plan for the extension of preventive services to the entire target population at risk to adolescent pregnancy? In regard to the President's initiative in adolescent pregnancy, I think you testified a few months ago you had reached less than 20 percent of the target at risk under the provisions of the bill the President has sent up here?

Dr. RICHMOND. What we are proposing in the measles initiative strategy is that we move toward reaching that entire population.

Mr. SCHEUER. I understand that. What I was suggesting is that in the President's adolescent pregnancy and health services bill you were providing family planning services for less than 20 percent of the American adult women and teenagers who are at risk and who have no services now.

What I am asking you is, why don't you have the same goal of phasing in preventive services that will reach the entire target population at risk for unwanted pregnancy as you do apparently for the entire targeted population at risk for measles?

Dr. RICHMOND. This is our goal, and I think, Mr. Chairman, that our strategy is to move up incrementally so we can reach that entire population. What we would like to do is to move toward including more each year.

I don't think we could do it in one year, but your goal is our goal. I don't think we have any conflict of objectives.

Mr. SCHEUER. This is an area in which Tony Beilenson has a great more expertise than I do. Do you want to interject here, Tony?

Mr. BEILENSON. It's the problem you mentioned before of choices and the limitation of resources, and these people obviously are seeking to eliminate measles prior to the time they seek to eliminate unwanted pregnancies. If you gave the choice to me, as you said earlier you would, I might have gone in another direction.

Mr. SCHEUER. Do you have a reaction?

Dr. RICHMOND. Yes, I would react. I don't think we are making that kind of choice. I think we want to do both.

Mr. BEILENSON. But we cannot do everything. That is what the Chairman said.

Dr. RICHMOND. But we are making a choice in relationship to measles. We think we are close enough to eliminating that.

Mr. SCHEUER. You have made the choice in measles, but you have not made that choice as to unwanted pregnancy.

Dr. RICHMOND. If the resources are available we will move as rapidly as we can.

Mr. SCHEUER. Oh, but, Tony, do you want to? I mean you have really opened your chest to the spear. You are saying in effect with the current finite limitation on resources, you are opting not to serve over 80 percent of the young adolescents who are sexually active, who are at risk, and who do not presently have services.

Mr. BEILENSON. What is worse for a young woman, to get measles or have an unwanted pregnancy? Those are the kinds——

Dr. RICHMOND. In a democratic society, that is how the choices are made in the Congress. That is what I am suggesting.

If you elect to give us more resources, we have no objection to trying to serve the entire adolescent population.

Mr. SCHEUER. Why don't you come up and ask for the resources? You have a lot of friends up here. It's difficult for us when you don't ask for the resources, Mr. Secretary.

Mr. BEILENSON. Does it cost a lot to immunize against measles or is that not terribly expensive?

Dr. RICHMOND. Our estimate is a relatively modest one, in terms of dollars. We think with an additional $5 million we can accomplish this task. The adolescent pregnancy program, as you recall, is $60 million, as we recommended it.

Mr. SCHEUER. And you would cover, as I recall you testified a few months ago, less than 20 percent of the people at risk.

Mr. BEILENSON. Actually, for the $60 million, Mr. Chairman, it's not at all clear, if I may say, that any of the $60 million goes to providing direct services at all. That is for coordinating services where, in fact, they do exist, and there is only, as I recall, a retargeting of $18 million, $10 million of which was taken from adult people at risk to give greater coverage to teenagers, but since the measles only cost $5 million, I don't suppose we should argue.

Mr. SCHEUER. I want you to know the Mutt and Jeff act is spontaneous and unrehearsed, Mr. Secretary. We did not plan it this way, but I am glad it happened.

Why is it seemingly impossible for the administration to come up here and say we have a 1982 target for reaching all of the target population at risk of unwanted pregnancy, and we are coming in with a phased program that will go over 4 years.

The first year we are going to reach a little under 20 percent of them, and the second year an additional 25 percent, and a third year an additional 30 percent. And we are going to do it through a combination of neighborhood based single service and comprehensive clinics, and this is our program and it will reach the entire targeted group by 1982.

Why does not the administration come up with a program like that?

Dr. RICHMOND. I think that is the strategy we are working toward.

Mr. BEILENSON. Why don't you present it, if I may suggest, Mr. Chairman, as a way of eradicating measles? If there are all of these unwanted children who are not born, if we prevent their births, they are people obviously who won't be able to get measles, so we will cut down on the target population we will have to immunize.

Dr. RICHMOND. There are fewer that need to be immunized by about one-fourth, if we go back to 1965, with the reduction in the birth rate. So that has been happening.

There is an overall reduction in the birth rate by 25 percent since 1965.

Mr. SCHEUER. Among adolescent females?

Dr. RICHMOND. Totally.

Mr. SCHEUER. I know there has been a substantial reduction in the 18, 19, perhaps even 17-year-old group. But the one group of females in American society where there has not been a lowering of fertility rates is the very young adolescent, and we think that is an obvious target group. We are really puzzled to understand why the administration has not moved to cover this group.

On any cost/benefit analysis, the cost, not only to the young girl but to society of a pregnancy of a 12-, 13-, 14-, or 15-year-old girl is devastating, it wrecks her chances to complete her education, and 90 percent of the 15-year-old girls who become pregnant don't complete high shcool. I think half of them don't even complete eighth grade.

Their chances for education are virtually destroyed, and their chances of a satisfying career in the job market are severely crippled. Their chances for a happy marriage are challenged. By your own testimony, we are spending about $4.6 billion a year in AFDC funds for women whose first pregnancy is during their teens. You are talking about billions and billions of dollars; "for the want of a nail the kingdom was lost."

We are talking about the expenditure of $75 a year to assure that these girls will get through their teens without an unwanted pregnancy. If there was ever a cost/benefit situation, that almost drove you to providing the services because of moneys saved at the Federal, State, and local levels, this would be it.

Your $4.65 billion of AFDC funds didn't pretend to include expenditures that we are also making at the State, county and muncipal level in support of both the women and these young girls and their children.

I don't know how you measure the cost of the destroyed lives. I don't want to seem paranoid on this subject, and this is not the hearing for that subject.

Dr. RICHMOND. Mr. Chairman, I would only comment that this administration did support this bill. I don't think this kind of bill has been introduced heretofore. It's very heartening for us to hear that there is so much congressional support. Perhaps we should come in for a larger request, but it is a first.

Mr. SCHEUER. The reason is, Congressman Beilenson and I are fiscal conservatives, well known fiscal conservatives.

Mr. BEILENSON. For those who know us well, you mean.

Mr. SCHEUER. Of course, and we think spending $5 billion at a very minimum on the support of women and their offspring, generally born out of wedlock, whose first illegitimate birth was in their teens, is not a very intelligent expenditure of Government funds, when an infinitesimal fraction of that amount might have saved these moneys and enabled these girls to have had happier and more productive careers.

Mr. BEILENSON. Mr. Chairman, I don't think the doctor's statement should go unchallenged.

This may not be the place to argue and the doctor is probably not in charge of that sort of thing, but, in fact, I think it's fair to say the administration has not been supportive of greatly increased funding for provision of family planning services.

The only thing they have strongly pushed is the so-called teenage initiative, and it's not at all clear to many of us interested in the problem that it's even aimed directly at the provision of those services. They were not supportive of the additional funds which the Congress itself authorized and, hopefully, will appropriate for direct provision of family planning services, et cetera, for adolescent or older women.

The only thing they are pushing, to repeat, is this $60 million program for, coordinating services which, as I said earlier, may or may not exist, and which it is not at all clear are even for providing family planning services per se. So I think he is not stating the administration's position.

Mr. SCHEUER. I think we should suspend and catch this vote. We will suspend for 10 minutes and we will reiterate how pleased we are to have you here this morning, Mr. Secretary.

Dr. RICHMOND. I am very pleased to hear this support for the programs I have supported for all of my life, Mr. Chairman.

[Whereupon, a short recess was taken.]

Mr. SCHEUER. Doctor, please proceed.

Dr. RICHMOND. I think, Mr. Chairman, I made a comment, in response to your last remarks, that we share goals. Perhaps we didn't ask for as much support as we might have, but I certainly will take your suggestion and see if we can come in for more support in the next budget cycle.

Mr. SCHEUER. What is wrong with coming in for some more support now? The President's initiative on adolescent pregnancy, the tail has been tagged onto the pony in the Senate side, so it will probably be considered in conference no matter what we do on the House side.

I hope very much to be a conferee. I would like to have some expression of the administration's wishes in this matter, and I hope they could up their sights. I would rather have no bill than a bill whose consequences are trivial because that indicates a perception on the part of the administration that this thing is so low in their hierarchy of values that it is just a window dressing or a Band-Aid.

It would be my inclination—well, I don't know which way I will go—but I would have doubts about adopting a bill that had such a low level of goals and aspirations and went no further than meeting less than 20 percent of the need for services.

I would almost rather start out fresh next January and hold hearings, trying to identify the need, have you come up here, identify the market to be served, the constituency at risk, just the way the administration did when they came to us last year on swine flu. They identified the constituent to be served. They didn't tell us to serve less than 20 percent of it. They wanted us to provide a program that would meet the entire need.

I would almost rather start from scratch with a tabula rasa than to engage in window dressing and trivialities. So maybe you could get some expression up to us of the kind of funding levels that would be necessary to do the full job over some intelligently phased period, and we would very much welcome that.

Congressman, do you want to add a word here?

Mr. BIELENSON. I don't think so.

Mr. SCHEUER. OK, please proceed.

Dr. RICHMOND. I think we will just respond to your questions at this point, Mr. Chairman.

As I indicated, my complete presentation is available but unless you want me to proceed with that, I think we would prefer to respond to your questions.

Mr. BIELENSON. If I may, Mr. Chairman, may I ask a couple of relatively naive questions about the Office of Health Technology?

I missed the first in the series of three hearings and there may have been some things explained at that time relative to what you are attempting here, so forgive me if the questions have been asked before.

Is this something which you people, HEW, started on your own which is now being either mandated or followed up in this legislation that I guess is in conference now, both Senate and House bills? Is this an initiative you undertook on your own or was it required by law, the establishment of this office?

Dr. RICHMOND. We proceeded, Mr. Congressman, to establish the Office administratively because we did see a need. However, I think it is fair to say it is like so many good ideas; there is a time at which there is consensus for action.

As I indicated to you, it is a problem with great complexity. Various groups around the country were struggling with how one could order this process and establish an office which would deal systematically with the whole problem of knowledge development from research all the way to applications, how we could order the process, and how we could engage in decisionmaking that would be more productive than the kind of random approach that has prevailed in the country until this time.

Mr. BEILENSON. I understand the need or the perception of the need and what you are trying to do, but my questions go to the end result.

What kind of powers, if any, would this Office have? What specific kinds of functions? What kind of end effects do you think its existence may have?

You mention in your testimony, in the prepared statement, on page 8:

> When fully staffed and operational, the Office will promptly select four to seven technologies that will receive a comprehensive assessment, including evaluation of cost and societal implications.

Could you give us some guess as to what some of those technologies might be, and perhaps tell us briefly what the end effect might be? When you come to a conclusion, in other words, about the cost effectiveness of a new technology or whatever, what then happens? What can you do?

I am asking too many questions. What could you do if your Office had been established at a time when the CAT scanner technology was first developed or what can you do about them now?

How do you foresee this Office actually functioning?

Dr. RICHMOND. Mr. Beilenson, I will be glad to make some introductory comments and perhaps my colleagues might want to make some comments as well.

We feel on the basis of the kinds of assessments that this Office could make, drawing on the expertise in the agencies that are in the Public Health Service, as well as the best expertise we can recruit from around the country, we can come to make judgments concerning some of the technological developments. We anticipate that those judgments certainly would be very useful to the Health Care Financing Administration, for example, whether reimbursement for certain kinds of procedures should be undertaken.

Although in the private sector we don't have any direct regulatory impacts, indirectly I think we might very well have. For example, third-party payers might draw on the kind of consensus and expertise that is offered through this Office.

We also anticipate that through the expertise that the Office brings to bear on these problems, that the FDA, for example, might use the consensus developed to decide the directions in which it might go for certain kinds of regulatory activities. It does have regulatory responsibilities.

Mr. BEILENSON. May I interrupt for a moment?

Dr. RICHMOND. Yes.

Mr. BEILENSON. Quite plausibly I suppose if the Health Care Financing Administration (HCFA) made some reimbursement decisions based on your Office's findings, and HEW's support of those findings, that might have a great effect even in the private sector.

Dr. RICHMOND. Yes.

Mr. BEILENSON. Does HCFA have the ability without congressional involvement to make some of these kinds of reimbursement decisions based on knowledge or conclusions that the Office of Health Technology might come up with?

Dr. RICHMOND. Mr. Derzon, I think, can comment on that.

Mr. SCHEUER. We would like to have as much input from the other members of the panel as possible. I hope you will all feel free to break in and give us your views.

Mr. DERZON. I think your question, Mr. Beilenson, is very much on target. We have participated with the Public Health Service in developing the concept of an Office of Health Care Technology.

We have traditionally, particularly through the medicare program, referred what we have called coverage questions to the Public Health Service. We have had to go to various branches within the Public Health Service to get specific answers on, for example, medication therapy.

We might have gone to the FDA on certain facets of the End Stage Renal Disease reimbursement questions. We probably would have also gone to the Center for Disease Control (CDC) because they are knowledgeable. We have gone to NIH and its various branches.

Under the new arrangements, we will go to one clearinghouse for a variety of problems related to coverage. The programs that I am responsible for, medicare and medicaid, raise many, many questions about what is medically necessary, because under the Federal statute we are supposed to pay only for that which is medically necessary.

Once this office is functioning, it will replace our informal practices of the past. Currently, we receive answers from the Public Health Service and, if we feel they have not looked at all the dimensions of the issues, we may refer the question again. In addition our staff often consults with the Public Health Service as it develops a viewpoint on coverage.

After we reach an agreement, we then instruct our carriers and intermediaries that we will now pay for a particular new service or new technology. That is precisely, incidentally, the way we handled the CAT scanner problem. We began only recently to cover certain body scanning procedures for certain selected diagnostic conditions that were predetermined appropriate by the Public Health Service by examining the scientific literature and discussing it with experts.

Mr. BEILENSON. You are not underwriting the whole panoply of scanner services that some people are attempting to offer?

Mr. DERZON. No; but we will continue to appraise what changes are taking place, because we know that obviously some scanning is very important and very critical to the welfare of patients. As science finds new ways to use the scanner appropriately, we would obviously begin to provide more coverage for additional diagnostic conditions.

So essentially we are very dependent on a strong component within the Public Health Service to assist us for we feel we could never duplicate that kind of expertise in the Health Care Financing Administration, nor should we.

I might point out that once these determinations are made, we have other devices to communicate this information to organized medicine, and to hospitals. One of those is through the PSRO system which, where it is functioning, has begun to look at the appropriateness of care for our beneficiaries based on evolving standards.

We also believe that, selectively, some PSRO's do offer a good fundamental basis for providing educational services and doing medical care evaluation. We do not have effective PSRO's throughout the country, as you probably know.

The decisions that are reached by the Government with respect to coverage are looked at carefully by the private insurance world. We also look at activity in the private insurance world, and are trying to develop a collaborative relationship with these insurors because we both have the same sets of problems.

So I think it is feasible, as we get more adept at these kinds of determinations, that more sensible decisions will be made about coverage.

I want to make one last point, and that is, technology will develop regardless of whether one or another insurance company or public program pays for it.

Obviously if we pay for it, we facilitate its introduction, but the CAT scanner is a useful example of this point. CAT scanning was in use preceding decisions of insurors to pay for that service. That was because either physicians felt it was an extremely useful device or the public started to demand it. People will obtain services for which they have to pay when coverage under insurance plans is not available.

Dr. WELLS. Are you suggesting that the great rash of CAT scanners has been individually financed throughout this country without third-party payment?

Mr. DERZON. At the outset, certainly the CAT scans were primarily financed through borrowings, both in private offices and in hospitals. The users proceeded to some extent in the early stages without any certainty that third parties would cover that service.

I think the strong advocates of CAT scanners and their usefulness to patient care and patient diagnosis genuinely believed that sooner or later the insurance industry, the Blues and the Government, would begin to pay for it. There was obviously enormous pressure on the medicare program to begin paying.

Dr. WELLS. One more question, Mr. Beilenson, if I may.

In Mr. Beilenson's state of California alone 100 CAT scanners have been placed and they are heading towards 200 and obviously it has not been financed by individuals out of their income, it has been financed by third-party payment. The testimony in the last hearing prior to this was clear on that point.

Mr. DERZON. I didn't mean to give you the impression third parties were not paying for CAT scanning. The Federal Government, I believe, a year and a half ago, started paying for head scanning, and this August 1, we began to pay for certain body scanning. Other insurers may have made individual decisions much earlier.

Dr. WELLS. Thank you, Mr. Beilenson.

Mr. SCHEUER. Has there been any facing up to how you ration CAT scanners and how you provide some kind of rational plan for providing that service without having a CAT scanner in the office of every private practitioner or in every neighborhood clinic?

Mr. DERZON. I would be glad to touch on this, and perhaps Dr. Richmond would like to talk about it as well.

First of all, most CAT scanners came in at the very time that health planning was developing and often preceded the ability of States to have certificate of need laws in place to control the placement and introduction of CAT scanners.

The planning agencies in some States do in fact have jurisdiction over CAT scanners, where certificate of need is in place. However, not every State has these laws.

There are very few States that I am aware of that have enacted special certificate of need legislation that would cover high-technology equipment, including CAT scanners in physicians' offices. The Congress, of course, is facing this issue with the Planning Act extension legislation which is before you. I think it is the view of the Department, and certainly my own, that you should control high technology in physician's offices. It is pointless to just regulate hospitals when you are dealing with issues like CAT scanners.

Mr. SCHEUER. Dr. Novitch, hasn't the FDA made known some findings and views about the use of CAT scanners and head scanners?

Dr. NOVITCH. Yes, about those, and a number of other radiation devices, Mr. Chairman, through a program of information education being carried out by the Bureau of Radiological Health.

Mr. SCHEUER. Do you want to tell us briefly what those findings are?

Dr. NOVITCH. I don't have that information with me, Mr. Chairman, but I would be happy to supply it for the record (see appendix p. 318).

Mr. SCHEUER. OK.

Dr. NOVITCH. In response to Mr. Beilenson's question, I would like to comment that the end product of technology assessment is very important to the Food and Drug Administration, and that we have in place a very good system for disseminating information on medical technology through the Drug Bulletin, which covers more than drugs.

On the subject of radiology, the University of Washington has conducted a very interesting study of the use of skull X-rays in two teaching hospitals in Seattle. The work was supported by a research contract awarded by FDA.

In one hospital, which served as a control, emergency services were allowed to continue as usual. In the other, careful criteria were developed to determine which patients would receive head X-rays.

Among the factors were history of coma, unconsciousness, clear signs of injury and the like. In the hospital where these criteria were employed the number of head X-rays decreased by 40 percent. In the control hospital, the number of head films actually rose during the period of the study.

I think this shows technology assessment can yield some very positive results, results which will appear in a forthcoming issue of the Drug Bulletin. The principal findings of the Seattle study are known to most radiologists, but FDA can help make them more widely known to the health community and that can result in some very dramatic savings.

The United States spends a quarter of a billion dollars a year on skull films alone. You can imagine the saving that could be realized if the results of this study were extended nationwide.

So I think we have an example of how technology asessment can proceed not only to dissemination of information but to significant actual cost reduction.

Mr. BEILENSON. Obviously what is being undertaken here is good and useful and is a rational kind of thing, but the question remains as to exactly what the end product will be in terms of savings.

I am new at the Federal level. Am I correct in understanding that there is no really direct Federal role in terms of health planning? It is left up to the States, basically, isn't it, except in terms of reimbursement decisions you might make?

Mr. DERZON. I am not the most expert person in HEW on the Health Planning Act, but I can tell you I think the effort in the legislation was to balance local interest and local planning——

Mr. BEILENSON. Which legislation?

Mr. DERZON. I am talking about the Federal Health Planning Act, which puts in place the health service agencies in each locality in the country. It requires State approval and the Secretary's approval of those agencies. The Secretary can withdraw that approval. The State has balancing powers because it is required to establish its own State health plan and so forth.

So the State does have lots of authority.

Mr. BEILENSON. We don't have specific authority at the Federal level, do we, to disallow the use of certain technology, the building of certain additional hospitals or whatever?

Mr. DERZON. I think we would have to get our experts to answer that question.

Dr. RICHMOND. I think we do. We have published some guidelines which deal with resource allocation, hospital beds, number of cardiac surgical centers serving various populations. The HSA's are the bodies which try to implement this through State regulation, largely.

Now if HSA's do not move in the direction of implementing these guidelines, the Federal power is largely in the direction of not funding those agencies. So it is not——

Mr. BEILENSON. But not prohibiting the construction of the hospital, or the purchase of the CAT scanner? People are free to go ahead and do that?

Dr. RICHMOND. If an HSA proceeds to recommend approval of hospital beds beyond what are in the guidelines, the Secretary looks very critically at that, and that could be justification for not funding that health systems agency.

Mr. BEILENSON. But not prohibiting that private doctor or hospital in Los Angeles, or wherever it might be, from doing whatever he or they want to do, right?

Dr. RICHMOND. If they are not in conformity with the State law, yes.

Mr. DERZON. There are substantial sanctions available and one might be that we would not pay for nonapproved facilities and services.

Mr. BEILENSON. Has it happened?

Mr. DERZON. Yes; under section 1122 of the Social Security Act where we did not pay for depreciation, interest, and other related expenses on projects that were not approved properly. This will happen wherever a planning agency makes a decision not to approve something that is within its jurisdiction.

I do want to explain that the Federal Government probably has authority under the act that it has not exercised in this area, and I will give you an example.

We have been looking into the question of mobile CAT scanners and whether or not we can require planning agency approval as a condition of allowing mobile scanning. Mobile scanning is now a useful, safe, and effective method of getting scanning services to smaller hospitals that need it.

Mr. BEILENSON. So each one doesn't have to acquire its own.

Mr. DERZON. Exactly. We would like planning agency approval before we authorize payment to that institution. The problem we face in the regulations currently is that the States have the right to determine what is an institutional service, and if a State determines that this is not an institutional service, then it would not be covered under the Planning Act.

So we would have to amend our regulations, which I understand we have the authority to do, namely, to stipulate what are the institutional services.

I do think an examination of the law would allow the Federal Government considerably more latitude to make decisions in this area if it chose to.

Mr. BEILENSON. That is encouraging. We are getting a little far afield. Let's go back and be specific for a moment, if we may, Mr. Chairman.

Perhaps Dr. Perry, or whomever, might pick up on Dr. Richmond's statement, where you said you might start off with a small handful, four to seven technologies, that you promptly selected for evaluation of societal implications and a comprehensive assessment.

Can you give us an example of, perhaps, one or two or three of the kinds of things you are talking about, and then take us through it and show us, if you decide at the end that the implications are such you don't think this thing should spring up all over the health care systems in the United States, if there is some way, perhaps, we could control this expensive disease of medical technology?

Dr. PERRY. If I might, I would like to respond to that by briefly telling you how we envision the Office of Health Technology will function.

I think putting this Office in place will for the first time provide a forum in HEW, particularly in the Public Health Service, where the strengths of the various agencies can be brought together and coordinated with the aim of assessing technologies, not only those already out in the practicing arena, but those that are about to enter the delivery system.

Mr. BEILENSON. I understand that, and it is terrific and everybody is for that. What happens when you evaluate them and they are found to be marginal or worthless?

Dr. PERRY. The responsibility of the Office will be to get the best assessments as appropriate—scientific, economic, societal impact, cost, and so on—and convey those recommendations to HCFA in the reimbursement area, to the health systems agencies for planning purposes, to the PSRO's, and to the practicing community and others that need to have this kind of information——

Mr. BEILENSON. You will be aggressive in getting these conclusions out once you arrive at them?

Dr. PERRY. Yes. As I have said, the agencies already have great strengths for conducting an assessment. They also have strengths in the dissemination of information. As Dr. Novitch commented, the FDA bulletin is one such resource and is an excellent mechanism for information dissemination.

Mr. BEILENSON. The important thing is beyond that. You have good assessment and good dissemination, what is the end result? Are we going to save some money or preclude——

Mr. SCHEUER. In other words, how does the loop function? How do your views and perceptions get cranked back into development decisions——

Mr. BEILENSON. And nondevelopment, even more importantly.

Dr. PERRY. For example, the CAT scanner that was discussed earlier. Here is a marvelous device and a great advance in diagnosis. It spread through the marketplace at a very rapid rate for a variety of reasons, including economic incentives. But I think there is now general agreement that it is being overutilized. In my view and in the opinion of others, there are not that many patients in the country who present sufficient indications to warrant a CAT scan of the head.

So what it has meant, then, is that a tremendous amount of money has gone into paying for CAT scans. But the principal point is that the criteria for the utilization of this device have not been spelled out and are only now beginning to evolve. There has been no formal mechanism in place where an outstanding group of experts and others could say this is how the CAT scanner should be used, based on our current state of knowledge. Based on those criteria, reimbursement is warranted, but not beyond that.

Mr. BEILENSON. HCFA would have the authority without further legislative involvement to make those reimbursement decisions——

Mr. DERZON. Yes; we have the mandate under the Social Security Act to make those decisions. When we get recommendations from the Public Health Service, we can accept them, and I think in a vast majority of cases we would. We can challenge them and send them back for further work. We can then act on the specific terms of coverage and then, of course, we implement.

I do think Dr. Perry made a crucial remark about the problem of utilizing technology appropriately. That is a hard job because the devices we have in place now are evolving and imperfect, and the decisions are difficult for all payers of health care services.

When to use these expensive technologies and controlling the use of them, it seems to me, are two of the most difficult and most crucial issues.

Mr. BEILENSON. Let me ask a specific question.

Let's assume Dr. Perry's Office of Health Technology was totally in place and going full steam 3, 4, 5 years ago when the CAT

scanner thing started erupting. And you had evaluated the potential use of the scan, full body and head and whatever, and you came to the decision it was useful and made sense economically, in terms of health benefits, in a certain limited number of instances, but not in others, and you made the findings public, and everybody from the different public health groups and your group were in agreement on that, and you disseminated that information widely to everybody.

Could that have had any effect whatever with respect to health planning, generally, throughout the country, very specifically in terms of the number of CAT scanners that were going to be OK'd by health planning agencies, assuming those agencies had all been in place at the time, too?

Would there be fewer CAT scanners in this world now if you had been there then?

Mr. DERZON. I think there would have been fewer CAT scanners now had that activity taken place, provided the Planning Act had been buttressed and in place too.

Mr. BEILENSON. Right now, say it happened right now, with the things the way they are now, with health planning, with its existing strengths and weaknesses, the Federal involvement to its existing extent, and the assessment people were in place, and they come up with these conclusions about CAT scanners. Do you think 5 years from now that we would have fewer CAT scanners in the United States than we actually do now if this had happened 5 years ago?

Mr. DERZON. Yes.

Dr. RICHMOND. I think the point Mr. Derzon made earlier about closing the loop in relationship to physicians' offices and other settings, in addition to hospitals, would be important. I think the health systems agencies have the potential power.

Mr. SCHEUER. We will suspend for about 10 or 12 minutes and catch this vote.

[Recess.]

Mr. BEILENSON. We will proceed for a bit, if it is all right with everyone.

It might be useful if you gentlemen might be able to file with the committee later, for purposes of the record, a list or description of the authorities that already do exist with respect to translating our findings into effect, as it were, the kinds of authorities which are extant that allow you to make some kinds of useful health planning decisions.

Dr. RICHMOND. Mr. Derzon and I would be pleased to do that, and it is certainly very important for the development of this office to have a systematic record. We would be glad to compile that. (See appendix p. 300.)

Mr. BEILENSON. Thank you. It would be helpful to have a feel of what the Federal Government can do, is empowered to do, and if that leads us to believe that something additional is desired, we can discuss it at that time.

Let me come back one more time; I am being persistent and am picking up on Dr. Richmond's statement. Is it possible Dr. Perry, for you to identify, without necessarily committing yourself, some particular technologies that your office might first be interested in

taking a look at so we have some feel, related to the real world, for what it is that you might be involved in?

Dr. PERRY. I think there are a large number of potential candidates, including those that are already out in practice, such as the whole area of end-stage renal disease, for example renal transplantation, hospital dialysis versus home dialysis, et cetera.

Mr. BEILENSON. So you are not going to limit yourself to evaluation and appraisal of new technologies but also existing ones, how they can best be utilized and perhaps discouraged from proliferating, if that is the conclusion you come to?

Dr. PERRY. I think it is fair to say that assessing emerging technologies will be more difficult than assessing existing technologies in that we will have to maintain surveillance and monitor developments not only in the academic sector but in the industrial sector.

Mr. BEILENSON. I also guess it is harder for you to forecast what is going to happen. It is easier to look back at mistakes made in the medical world and say with 20/20 hindsight we shouldn't have allowed this to proliferate as much as it has, or have purchased in the kind of quantities and the amounts it has been used, because clearly its benefits are marginal in many instances.

Dr. PERRY. I should comment on another facet of the new mechanism which has been put into place.

The discussion this morning has been related to activities and recommendations that might emerge from the new Office that would tend to limit the dissemination or utilization of technologies.

I think it's also fair to say there might be circumstances where the office would act in a positive way. If some new development came along that held great potential and had been proven by clinical trial to be safe and effective, we might play a positive role in disseminating such information.

Mr. BEILENSON. That is a very useful point for you to bring to our attention, because we have been I suppose thinking much in the negative about this sort of thing. That would be a useful function for you to perform.

But, frankly, we really need some negativism in this area, too.

Dr. RICHMOND. Mr. Beilenson, if I might comment. We are trying to develop some processes whereby we can anticipate developments rather than coming in after they already have emerged. I think it's to the credit of the staff of the NIH, for example, that they have set up a series of consensus-building exercises trying to take a look at developments in the various Institutes in the fields that are relevant to their work to see if one can anticipate what might be coming down the line and to see if we can then either enhance the development of testing or undertake whatever critical review might be necessary.

Mr. BEILENSON. Just one more question, if I may, with respect to following up on something I mentioned and also I think Dr. Perry mentioned, and that is end-stage renal disease, and the fact we are now approaching perhaps a billion dollar a year expenditure for treatment of that problem alone.

It's apparently 40 or 50 percent as expensive to have the home treatment as it is to have institutionalized treatment. I take it the Federal Government pays for that entirely, does it not?

Dr. RICHMOND. Yes; to the extent authorized under the medicare program, 80 percent.

Mr. BEILENSON. We ought to have a lot of leverage. Is there some effective and useful way that the Federal Government can see to it that home dialysis becomes the usual form rather than the other way around as has been developing in the past 2 or 3 years?

Mr. DERZON. I would like to respond to that question because the medicare program is almost the sole buyer of end stage renal disease services in the United States, and our estimates of future program expenditures of close to a billion dollars are rapidly becoming a fact.

The Congress passed legislation Public Law 95-292, which we very solidly supported this past year, and we are now busy putting together the implementing regulations. The purpose of the end stage renal disease amendments, primarily, was to expand the proportion of patients on self-dialysis and to increase the numbers of kidney transplants for patients who have chronic renal disease. Transplantation is another potentially less expensive and often a very satisfactory treatment of chronic renal disease.

The new law provides strong financial incentives to patients to undertake self-dialysis and we are trying now to work out reimbursement techniques that will make it just as advantageous to treat patients in their homes and self-care settings as in facility units.

We are also looking at some demonstration ideas about how to expand the rate of transplantation, and at the transplantation sections of that act which make it possible for the full cost of transplantation to be covered by the medicare program.

This is a complicated area for a number of reasons, but clearly there have been, up to now, very powerful financial incentives to keep patients in facility dialysis units.

Mr. BEILENSON. That will change, in your opinion?

Mr. DERZON. I think the new legislation affords us an opportunity to have those changes take place. I think we have to wait and see whether, in fact, a substantial number of patients get treated on home dialysis or in self-dialysis settings as a result of that legislation. Clearly it's our intention to administer that law so that a much larger proportion of the patients find their way into self-dialysis settings. That is roughly 50 to 75 percent of the cost of facility dialysis.

Mr. SCHEUER. When you say "administer the law so that more patients find their way onto home dialysis," will you explain just what you mean by that?

Mr. DERZON. Exactly. I will be happy to.

Mr. BEILENSON. That is, why can't we be more sanguine about the essential effects of the changes in the law? Why don't you tell us in fact that the balance will shift and a much greater percentage of people will be treated at home?

Mr. DERZON. Before the original end stage renal disease legislation, was passed, a center in Seattle had a rate of close to 90 percent of its patients on home dialysis and has been able to maintain something, I think, close to 70 percent since that starting date.

The number of new patients in other parts of the country who became eligible for treatment of end stage renal disease and who went on home dialysis has been running at approximately 10 percent. The decision as to whether a patient goes on home dialysis or to a facility rests with the nephrologist. It does not rest with the Government.

Mr. BEILENSON. That is the problem with all these decisions, they are all made by doctors. That is, all health care decisions. Mr. Scheuer's friend, Mr. Fuchs—that is his basic thing.

Mr. DERZON. I am not sure I have a response to that, other than to say that end stage renal disease is a complex illness, and I dare say it's difficult to find a substitute for a physician to make some of these decisions.

But I think it's a fair statement to say that the powerful financial incentives that make it advantageous for practitioners to treat patients in facilities are almost overwhelming.

Today, the nephrology community points out that the nature of patients with end stage renal disease is changing. Their argument is that we now have patients on end stage renal dialysis that are much higher risk patients; they are much sicker, they are patients we could not rescue in the past, and so forth. But then, allowing for that, it's very clear to us that 25 to 35 percent or more of the patients on dialysis in most renal centers ought to be able to go on self-dialysis.

The argument in Congress was whether or not to set a quota or percentage and force a greater use of self-dialysis. The Congress chose language that essentially allowed ESRD networks to set their own goals, and we will be monitoring, using the best authorities we can find, to see whether or not the networks and dialysis centers are actively and intensively engaged in trying to encourage patients to go on self-dialysis.

That is the reason why I say we have to administer this program properly in order to achieve this result. The Federal managers do not intend to intervene in every decision that is made in these matters.

The transplant surgeons, incidentally, believe many candidates are not being presented for transplantation. My hope is that we can do something about that issue. Although there may be some shortages of cadaver kidneys and related-donor kidneys, I am convinced that not enough patients are being referred for transplantation and that represents a serious problem.

Mr. SCHEUER. I asked you before to elaborate on your statement that you were going to manage this program so that more patients would find their way into home dialysis. Do you consider that you have just given us a description of a firm management program? What I get out of what you have just told us is you are going to monitor.

Do you call monitoring management?

Mr. DERZON. I think we manage in a variety of ways, one of which is by monitoring.

Mr. SCHEUER. Elaborate on how your management program is going to help more patients find their way into home dialysis? What are going to be the elements in the management program?

Mr. DERZON. Mr. Chairman, the first device we have is regulation, and we are writing regulations now. I think they are strong regulations that spell out very clearly the responsibilities of networks and dialysis organizations to achieve the goals of this legislation.

I think two or three of our five or six regulations have already been issued as notices of proposed rulemaking. That is our first management device, and a very critical one.

The second is that there is a network system established under the End Stage Renal Disease Act, and the review process for the acceptable care of patients rests, as Congress has prescribed it, with those networks. In a sense they perform a peer review function, looking at appropriate utilization of care.

Since we are financing these networks, we will have the obligation under the law to assure that there is the right kind of utilization. There are patients on that network board as well as physicians and other knowledgeable people, which adds to the usefulness of this particular device. In addition, the Government has its own staff of experts in nephrology, and we will be using them out in the field, together with those from the Public Health Service.

We have staff managing the end stage renal disease program in our 10 regional offices. I think we have a good management plan to accomplish that.

The heart of this issue, in my view, is one of economic incentives as well as individual medical decisions. I think it's very clear in this particular area, with a single buyer of services, that perverse economic incentives can bring about the wrong result and more positive economic incentives can achieve a better result.

Mr. SCHEUER. So you are talking at least to some extent about the reimbursement rates that have sort of pushed patients?

Mr. DERZON. Absolutely.

Mr. SCHEUER. Not only in renal dialysis but a whole bunch of other areas toward an excessively high technology entrance into the health care system.

Mr. DERZON. There is no question about that, in my mind.

Mr. SCHEUER. So you will be taking a good hard look at reimbursement rates to change its incentive structure?

Mr. DERZON. Yes; we are and, in fact, there are provisions in that new legislation that give us the authority to do just that.

Mr. SCHEUER. OK. Are you going to plan to have any funding for programs of training of both parents and the members of their family in using home dialysis so they can become comfortable with the idea and have some confidence they can cope with the requirements of home dialysis?

Mr. DERZON. The law provides this authority and also gives us specific demonstration authorities to look into the broad coverage of paid partners. We will exercise those demonstration authorities and report to Congress on the results. We will also be looking at the limited coverage of paid partners under the current law. We believe this is a very promising area.

Mr. SCHEUER. How about some kind of psychological counseling for the patient and the family to create an incentive for them to be treated at home in their own neighborhood atmosphere, among

their friends and families, and so forth? That is something that might have a payoff.

Mr. DERZON. Yes; it's an excellent idea. There is a very explicit provision for the payment of a full and adequate training of patients and for home support services, so that we can now directly reimburse for services that we might not have directly reimbursed for under the old legislation.

Mr. SCHEUER. I am making a distinction between training the patients and some kind of psychological counseling for patients to create motivation. It might be done by the same person who would train the family and friends in the actual operation of home dialysis equipment, or it might be done by some other person who is a health psychologist counselor.

Mr. DERZON. I think that is an excellent idea and I will go back to look and to make sure that we have provisions that allow us to do that.

Mr. SCHEUER. Now, how about the home dialysis machinery itself, the actual technology itself, is it really appropriate for home use or could there be a further refinement of the technology that would move more toward appropriate technology or somewhat less sophisticated technology that was especially designed for home use?

Mr. DERZON. Although some experts will argue with our conclusions about that, we have concluded that there is safe and effective equipment presently available for use in homes.

Mr. SCHEUER. I am not saying safe and effective, what I am saying is, is it so demanding in skills by the user or the user's aides that it really isn't appropriate in most cases for the patient and the patient's family to use it?

Might there be some refinement of the technology to produce, let us say, an alternate technology that is intrinsically less demanding of highly sophisticated medical skills, more appropriate for home use?

Mr. DERZON. Let me make a few points related to that.

The first point is, under the new law, we can pay in full for the equipment at home, whereas under the old law the patient had to pay substantial out-of-pocket costs, because it was reimbursed at 80 percent of the charge for the equipment. This law makes it easier for the patient to have this equipment and does not put him at a disadvantage financially just because he is not treated in a facility.

Second, the equipment has generally not been the barrier to home dialysis. It has been the sum of the psychological factors you presented. Most people with moderate intelligence can handle that equipment. But they need to be at home or in appropriate self-dialysis settings. Regrettably there are many patients with end stage renal disease whc do not have adequate homes, or do not have anybody at home who is willing to take on this responsibility.

Mr. SCHEUER. Now, you are talking about home visitor service of some kind. Is this going to be part of the mix?

Mr. DERZON. This is covered in reimbursement. I am going to check and file an answer for the record, but I believe this is covered. A facility that takes on a responsibility for a patient has a responsibility to assist that patient at home, to send technical help to make sure the treatment is working, to check periodically that

equipment is in order, to maintain the equipment or substitute other equipment for it, so that the patient is not left out there all by himself or herself.

So, that will be covered, as I understand it, under the new legislation.

[Material referred to follows:]

The present medicare law does not provide for payment for a "home visitor" to help a patient with home dialysis. Effective April 1, 1979, however, the recent amendments pertaining to kidney disease coverage under Medicare (Public Law 95-292) will provide medicare payment for the services of home dialysis aides as part of an optional "target rate" reimbursement method for facilities that oversee home dialysis patients. Under this option, if the Secretary determines that a facility can provide equipment, supplies and support services (including aide services) to its patients in an effective and economical manner, the facility would be paid a single rate covering all these items. However, the "target rate" cannot exceed 70 percent of the national average reimbursement rate (that is, the average amount approved by medicare before application of the coinsurance requirement), adjusted for regional variations, for institutional maintenance dialysis in the preceding fiscal year. Of course, this coverage would only be available to patients of facilities that have elected this payment option.

In addition, we are now making payment for home dialysis aides under an experiment with the patients of selected facilities. If the patient chooses to have a family member as a dialysis helper, payment is also made for those services, although at a lower rate than for a paid aide.

Mr. SCHEUER. Let me just take it a step further.

Let's consider the point where the patient's family says, as a matter of convenience and upset to us and our family routine, we would rather have our uncle, aunt, brother, or sister treated in the hospital; it's just less of a hassle for us.

Now you said before you weren't going to interfere in medical decisionmaking. As I perceive it, this is not a medical decision, this is a convenience decision. Do you feel that the Government or the taxpayers have the right to tell the patient and that patient's family and that patient's doctor, look, we are willing to pay for the cost of your medical care, but if the Government can't effect a substantial cost of savings in your health care by providing this health care at home, because it's inconvenient to you, then we are going to have to say, this is what we are going to offer, the health service at home, and if you want to go to the hospital you can pay for it yourself, or at least pay the difference between home care and hospital care.

The taxpayers of this country are not likely to approve that additional investment in hospital care simply because the home care would make some modest additional demands upon the family. We are going to ask you to discomfort yourself or inconvenience yourself. Since you have a very ill or elderly relative, we think it's reasonable for society to say that you must help and you must cope with this additional inconvenience, and we are sorry about that, but this is part of the social compact, let us say.

Are you prepared to undertake that amount of arm twisting or jawboning?

Mr. DERZON. First of all, I would like to point out that we frequently face these decisions in other areas.

As you know, you have frequently read or heard from a constituent who has been asked to leave an acute care hospital by a utilization review committee, or by a PSRO that decided this patient no longer needed this service. So the beneficiaries may stay in

the hospital a day or two, but then they must find another facility. We do not pay for services endlessly that a PSRO or utilization review committee does not feel are necessary.

I think we have probably not faced the problem as frontally in the case of end stage renal disease.

This is a very fragile group of patients, fragile in the sense that they are extraordinarily dependent on their physicians, their equipment and their facilities. I think we have a slightly more difficult problem with this group because these really are life or death issues.

It's very clear that a patient cannot afford even the difference between the costs of home dialysis and facility treatment for any prolonged period of time, simply because dialysis is so terribly expensive. Many of these patients are debilitated, cannot hold a job, and so forth.

I think I would have to give you a cautious answer. This needs to be addressed patient by patient, by physicians, clergymen, psychologists, and anybody you can bring to bear on the problem. I would not like to see the Government get extraordinarily heavyhanded, and I don't think we could defend that to the American people.

Mr. SCHEUER. Where it's a question of convenience and not the quality of health care, I don't know why you can't get heavyhanded, particularly with the relatives, who in many cases would constitute the real problem.

Mr. DERZON. I think the issue is that as you deal with these problems individually, you find out that it's never just a question of convenience. It's fear of being left alone and isolated, or having a problem with a piece of machinery, or the need for total dependence upon machinery. There are always multiple factors, in my experience, in dealing with this kind of a problem. I believe that it would never boil down in the last analysis to simply a matter of convenience, or at least it rarely would.

But I would agree with you, if convenience were the only issue, that the most strenuous means should be found to persuade that family and that patient to meet its responsibilities.

I do wish to comment, though, the experience in Washington State is that many patients really want to be as independent as possible, and that one is not always faced with the other side of this problem. In fact, very frequently, patients really want to be independent of health care givers. They want to do as much as they can on their own. They feel a real sense of responsibility, and they recognize the great costs they are incurring. A large group of patients given this opportunity of independence do want to take advantage of it.

Mr. SCHEUER. How do you explain the difference between the 17 percent of patients generally who are served at home and the 50 to 60 percent of the patients in Washington who are served at home?

Mr. DERZON. There is absolutely no satisfactory explanation for it.

Mr. SCHEUER. I think you have to come up with an explanation. I think somebody has to look at that experience and try and isolate the factors of motivation, or additional services of health extenders into the home, or whatever. There has got to be an explanation.

I think you ought to come and tell us what that explanation is and we ought to structure programs based on your finely honed analysis of what produced the incentive structure in the State of Washington that was so different from the incentive structure in the rest of the country.

Mr. DERZON. Perhaps I didn't speak as clearly on that as I intended. We believe that the differences clearly center around the factors of economics, of attitudes of certain physicians that differ clearly from other physicians on this issue.

But I think you are absolutely correct, that if it can be done in the State of Washington, it can be done anywhere else in the country, since patients are not that different in the Northwest from the Southeast.

Mr. SCHEUER. I would like to hold the record open here for an informal report from you or a memorandum from you, after you have had a chance to look into the situation in Washington and see if you can identify for us the structural elements of their program that seem to cut by two-thirds or three-quarters the number of patients who need hospital treatment.

Mr. DERZON. We will be pleased to do that.

[The information follows:]

The high rate of home dialysis in Washington is due primiarly to the large number of patients placed on home dialysis by the Northwest Kidney Center (NKC). The Northwest Kidney Center is participating in one of HCFA's home dialysis aide experiments, but as a control group facility only. Therefore, the NKC is not being reimbursed by medicare for home dialysis aide services.

The major reason for the NKC's success in sending patients home is the philosophy of treatment that is followed there. The facility's physicians and staff have a very strong commitment to home dialysis, and believe that it leads to a better quality of life for the patient. The assumption is that patients can and should manage their own disease to the greatest extent possible without constant medical intervention. The NKC therefore strongly encourages independence and self-care on the part of its patients, and all patients are considered potential candidates for home dialysis. The NKC emphasizes a thorough training program, and adequate supportive services once the patient goes home.

In order to get more patients home, the NKC has initiated its own paid aide program, funded by State money and donations, for the patients who have no home helper available. Approximately 14 percent of the NKC's home patients have a paid dialysis aide. The NKC did not seek participation in HCFA's experiments because the director did not believe NKC could significantly increase the percentage of home patients by participating.

Another reason for NKC's ability to get patients home is its frequent use of peritoneal dialysis. Approximately 17.5 percent of the NKC's patients are treated with peritoneal dialysis. This is a relatively simple technique to learn, and can sometimes be performed by the patient alone.

Mr. SCHEUER. You mentioned in the particular case of renal dialysis that you recognize the incentives, largely the reimbursement schedule, was the villain here, and that you were studying how to change that incentive structure to provide an inducement, or to remove the economic barrier, to the patient being treated at home.

Now, how about carrying that idea throughout the system of health services, far beyond kidney dialysis. We have had extensive testimony before this committee that it is the incentive structure that is really the villain in producing so much of this overutilization of high technology tools, systems, facilities and health services systems, and it's the incentive structure that sends a patient with a sore shoulder into a hospital, into a tertiary hospital bed costing

$250 or $300 a day on Friday afternoon when the system that put him there knows the first time that patient is going to see a doctor is Monday morning.

But they want those beds utilized over the weekend, and the hospital administrators are looking for a high patient load. The incentive is to load patients into high technology treatment, into tertiary hospital beds, when from the point of view of simple every day logic, which is what I bring to this hearing, those patients could be treated on an outpatient basis, on an ambulatory basis, by less sophisticated health personnel, and that this is wasting literally billions of dollars a year.

Now, what I am asking is, is it within the purview of our office to conduct a reappraisal of the entire reimbursement system which is pushing people into health care at levels of sophistication and cost demonstrably higher than really what is appropriate?

Mr. Derzon. I think it is HCFA's responsibility. I don't think we have the only responsibility within HEW, because a good deal of this work is done in the National Center for Health Services Research, and the Office of the Secretary, the HEW planning group, and so forth, but I can tell you clearly we have a responsibility and we are accepting that responsibility.

I believe financial incentives in reimbursement have contributed clearly to the too rapid rise in health care costs. I have testified in fact before other committees, on this issue.

Cost reimbursement itself keeps hospitals whole. It encourages hospitals to spend more money. We need to limit cost reimbursement. One of the proposals we have for doing that, of course, is cost containment legislation, which would force hospitals to make some choices. We would not reimburse hospitals providing more and more unnecessary services or providing higher levels of service than were absolutely necessary.

Mr. Scheuer. Don't we want to provide different incentives for physicians too, to treat people at home when it's appropriate rather than leaving the financial incentive structure that pressures them to put the patient in the hospital?

Mr. Derzon. Yes; I think that the way medicare pays for physician services is wrong, and about 6 months ago we made several statements before Congressman Moss that would be very germane, I think, to your question.

Fundamentally, we told him that the plan medicare follows, which is to pay usual, customary, and prevailing charges, simply prolongs the agony of a system that is very unbalanced. It inflates health care costs for physician services too rapidly. It pays a premium for procedural medicine and pays a discount for primary care medicine. This method ought to be changed.

We had some suggestions as to how that could be changed, through capitation programs, which tend to make more dollars flow to primary care physicians, and also through fee schedule systems that are negotiated and have a more sensible balance between primary care and specialty care.

To elaborate further, another factor clearly is the mix of physicians in the population. We have an imbalance, most of us feel, between specialty and nonspecialty physicians. Our studies show that physicians have an income expectation which they try to

realize and successfully do, at both our expense and the private sector's expense. We are interested in manpower policies that will reverse that proportion, and increase the numbers of primary care physicians rather than specialists.

I think you have to look at many, many factors, reimbursement being one of the major factors.

Mr. SCHEUER. Mr. Derzon, we are trying to look at all those factors, but we don't see that kind of approach being taken in the Department of Health, Education, and Welfare.

We don't see any top level, organized, systematic review of the entire health care system from the point of view of reversing all of those incentives and pressures that drive the patient into the system at inordinately excessive levels of cost, technology, and so forth, rather than finding the lowest level of technology, the lowest level of intensity of care, the lowest level of specialization of personnel, let us say, which is consistent with quality health care for that individual.

What I want to know is where is this comprehensive look-see going to take place? Who is going to provide the leadership? You have indicated that there are many places in the whole HEW family where they have a little slice of the action. But where everybody is boss, nobody is boss.

I want to know who is going to be the leader and the driver of this intensive comprehensive scenario of system analysis of a cost system that has gone beserk, of a cost system that has only an accelerator and no brake?

Mr. DERZON. I think that assignment is clearly in the Health Care Financing Administration. I do think a comprehensive approach is being taken to that set of issues.

Our advice is not always followed, and I am sure nobody in our agency would tell you we have all of the answers.

Mr. SCHEUER. Have you ever issued a single comprehensive report on how we should redesign and restructure the whole financial incentive system of government supported health care?

Mr. DERZON. We have provided at least one document which I think fulfills a large share of that bill, which is major legislative initiatives and strategy for the Health Care Financing Administration.

We are happy to provide you with that document.

Mr. SCHEUER. Would you do that, because that would be very helpful to us.

[The information was submitted (see appendix p. 310) for "HCFA fiscal year 1980–81 strategy:"]

Mr. SCHEUER. Dr. Wells?

Dr. WELLS. In our testimony on the 27th, Dr. Louise Russell, senior fellow of the Brookings Institution, gave us a rather dismal prognosis of what we could see coming in the next few years in the health care system.

Currently, about 9 percent of GNP is going into the total health care system. When asked if she didn't see this leveling off, stabilizing around this level, she was very candid and direct in saying, no, she did not, and that it was probably going to take something like, 12, 13, 15 percent of GNP before the American people would probably say, this is enough. She felt that the forces upward and

onward are far too strong to resist, and she introduced a perception of the individual demand for the best quality health care in the world. There is no incentive on the individual person not to seek the very best.

If this persists we will probably hit 15 percent of GNP before there is some kind of massive reaction.

What do you think about her forecast for the future?

Dr. RICHMOND. I am sure Mr. Derzon will want to make some comments on this. Obviously, there are individual interpretations. People have their own analyses.

The concern about the rise in the percentage of the GNP which is being expended for health care in the Nation is an important public policy issue. I guess I would not be quite as pessimistic about how long it is going to take for people throughout the country to become concerned. I think the very considerable interest in hospital cost containment at the present moment is a reflection of the fact that people are becoming very concerned.

If we look, for example, at the auto industry, the negotiations concerning fringe benefits, we have not only a labor concern, but we have a management concern. When you get those kinds of concerns being manifested in the Nation concerning health care costs, I think you have a growing consensus.

I have the feeling that we are getting close to the point at which there is a national concern. The very fact that this kind of hearing is taking place, and would not have taken place 10 years ago or probably not even 5 years ago, is significant. It's only within the last year or so that people generally have become aware of the rapid escalation in the health sector, far beyond the rate of general inflation.

So I think we do have to invoke the various regulatory processes which are made available to us. Hospital cost containment is the focus at the present time because it is the largest single component of health care expenditures. So if we cannot put a brake on it in some way and rationalize it, we won't make much progress.

Mr. SCHEUER. Dr. Richmond, my problem with the hospital cost containment bill, and I should say to you that I did support it in the committee, however reluctantly, is that it concentrates on caps, but does nothing about looking at the pressures that generate the need for the caps.

It is strictly a Band-Aid, and until you get to the business of getting down to fundamentals and analyzing why those cost pressures are there and why can't they be diverted and contained by making the whole reimbursement system more rational so that people who should be treated by any rational criteria on an ambulatory outpatient basis are treated that way, you are never really going to come to any solution of rising costs. The whole reimbursement system has to be more reational. It has to be essentially a market system that is self-operating.

Dr. RICHMOND. I think I might comment, Mr. Chairman. This goes back to your earlier comments concerning the quality of care, and the matter of primary care as being more appropriate for many people. But I think even in your comments there is a tendency to fall into the trap of saying not everybody can have high quality care.

My point is, and I think it's basically your point, that tertiary care is not necessarily high quality for many categories of patients.

Mr. SCHEUER. I could not agree with you more.

Dr. RICHMOND. And we need to find better ways of creating the very incentives you talked about so people may receive the appropriate and better quality care without going into hospitals. These are the kinds of issues we are struggling with in the Nation.

But I should also make this caveat. Most of the reimbursement systems we currently have historically derive from some of the insurance plans that developed earlier in the century, and which were designed largely for catastrophic kinds of problems. We carried them over into dealing with the entire health care sector. They are dysfunctional, and that is why we are struggling with the problem.

Mr. SCHEUER. These are the barnacles of the past, and we are going to have to scrape them off. Now, I presume you, that is the administration, are going to come to Congress, next year with another effort at hospital cost containment, right?

Mr. DERZON. We hope that won't be necessary, Mr. Chairman, because we still think it has a chance this year.

Mr. SCHEUER. You do? Really? Are you serious?

Mr. DERZON. Eternally optimistic. But I think it's a fair statement to say that it will be in the President's budget next year, at least we would recommend that it be if it is unsuccessful this year.

Mr. SCHEUER. Let me suggest to you that I think the administration has to get first things first, and I think to come up with a Band-Aid before you have come up with a comprehensive program of restructuring the incentive system and restructuring the reimbursement system would be simply not providing the kind of leadership that the country wants and Congress wants, and I would think it would be totally inappropriate if the administration comes up here on another emergency basis with a hospital cost containment proposal, absent having done something about all of these barnacles of the past, Dr. Richmond, that you just referred to.

Let's get down to the fundamentals. It was OK a few months ago. The President came to us on an emergency basis on hospital cost containment. Essentially, the kind of controls you can exert through hospital cost containment are on the margin, if you know what I mean.

I think we have to focus on the essence of the problem. We have all of the wrong incentives out there and I very much hope we will get some kind of a comprehensive, deep searching evaluation and analysis of the entire incentive structure, of the entire reimbursement structure, of all of these barnacles of the past that you properly referred to, Dr. Richmond, as an indispensible precondition of cost containment. Present proposals for cost containment are going to have effectiveness way at the margin and are not central to the problem really that we are discussing.

Mr. DERZON. Without being a tireless defender of cost containment in hospitals, Mr. Chairman, I have to say $30 billion to $60 billion is a substantial amount on the margin. It would extend the life of the hospital trust fund for medicare alone, probably 2, 3, or perhaps even 4 years from what it is now.

It represents a prospective reimbursement system in the sense that hospitals will know what they have to work with and will have to work within it. So it resolves some of the criticisms of the past. Congress has made many suggestions to substantially improve the cost containment legislation.

I think a careful look at what has been suggested will show that considerable savings can be achieved in hospitals. I would fully agree with you, however, that hospitals are only one piece of the whole pie. However, they represent 40 percent, which is not insignificant.

Mr. SCHEUER. Maybe they should not be 40 percent, maybe they should be much less. You are trying to redivide one little piece of pie where actually that piece perhaps should be a far smaller slice of the total pattern of health care expenditures.

Mr. DERZON. We know that in HMO's, the hospital share of costs is about half of what it is otherwise.

Mr. SCHEUER. But let's get on with it.

You are providing the seed of an idea, aren't you?

Mr. DERZON. Right.

Mr. SCHEUER. For very intensive analysis that ought, if it has not started by now, ought to start at 1 o'clock this afternoon. And so, by the time January or February comes around, you will be talking not just about how to reslice this hospital pie, but how to reslice the whole pie, and maybe cut the slice that goes to the hospital system itself by the 50 percent that you talk about. And the HMO's have proven you can do it without any reduction in the quality of care.

I think Dr. Richmond might even say at an improvement of the quality of care considering all of the psychological implications of being treated adequately at home as compared to the cold four walls of a hospital.

However, I don't want to put words in your mouths, Dr. Richmond.

Dr. RICHMOND. That's right.

Mr. SCHEUER. Let me just ask Dr. Perry—in all of these conversations, I think you get some sense of frustration. Now, the Office of Health Care Technology obviously has a function in evaluating technology from the point of view of safety and from the point of view of efficacy.

Will you also deem it within your purview and within your mandate to look at technology from the point of view of management strategies and reimbursement strategies, to promote the kind of technology that we need to develop and that is appropriate for neighborhood clinics, or for paraprofessional outreach people working from hospital outpatient care centers, reaching into the home, or appropriate for patients, appropriate for patients families, appropriate for visiting nurses?

Is this going to be part of your bag, so to speak?

Dr. PERRY. Our responsibility will be not to set standards for reimbursement, but to provide to those concerned with health care, recommendations on all aspects of existing or emerging technologies.

These recommendations will be aimed at providing the kind of help and guidance to the various agencies, whether it be FDA,

CDC, or others who have responsibilities in the marketplace, whether they are regulatory or reimbursement or whatever. In other words, the Office exists, as I said earlier, to identify the needs of the various agencies and to try to provide these agencies with the kind of knowledge and information that they need.

Mr. SCHEUER. Are you going to be, for example, advising NIH about the desirability of developing appropriate technologies, such as renal dialysis technolgy that is appropriate for the home, that is appropriate for the family members and the visiting nurse, the paraprofessional visiting nurse that does not have a lot of credentials?

Dr. PERRY. I am glad you brought that up because it has not really been mentioned thus far and that is that these exercises, these activities will identify not only the advances in the state of knowledge and the state of the advances, but also the needs and the gaps in the knowledge base. I think the activities at the NIH in technical consensus development over the past year have demonstrated this very fact, that is, that assessment activities work both ways, evaluating advances and identifying gaps in the knowledge base.

Through the forum provided by the creation of the Office, appropriate studies to fill these gaps will be fostered.

Mr. SCHEUER. I am not talking about gaps in the knowledge base for creating technology.

But I am talking about gaps in developing appropriate technology as we use the phrase in international development policymaking. That is, maybe for the developing world what they don't need is a concentration of steel mills and open papermills and petrochemical factories that are very capital intensive, that have practially no job implications.

Maybe what the developing world needs is truly more appropriate technology, cottage industries that are very labor intensive, that can be located in rural areas, that provide jobs for women. When women work and women get literacy skills they begin to change their fertility levels, and they have different family size goals.

We have run out of time, and I have got to make that rollcall vote. But I hope this will be part of your description of a gap, not only gap in existing techniques and facilities and services, but a gap in the kind of appropriate facilities and techniques and technologies that can be used at far lesser cost in the home by the family, by a visiting paraprofessional, the nurse.

Dr. RICHMOND. We are doing such studies, Congressman.

Mr. SCHEUER. Dr. Richmond, if you want to leave now you are more than welcome. I only have one more question, and if you want to continue talking after I leave, fine, if you want to answer it by letter, fine. If you want to stay for 10 minutes, which is about what it will take me, that will be fine.

The question I am going to ask is where is this all going to be pulled together, because I still see all of the many diverse members of the HEW family sort of going their own way, cooperating to some greater or lesser extent.

Where is this all going to be pulled together?

Dr. WELLS. Dr. Richmond, on the first page of your statement you identified the three major central problems.

To what extent will the new Office in the new structure you are devising deal with those three central problems, I think that is really the question of Mr. Scheuer.

Where you suggest many technologies have been widely adopted without sufficient information, will these now be adopted with sufficient information.

Second, the use of other technologies persisted long after it was evident they were of marginal utility, outmoded, or harmful. I presume the effort will be stronger measures to remove these.

Third, well validated innovations are slow to come in. They will come faster, in the positive aspect of the negative you presented.

Is that a fair representation of what you are seeking in the new Office of Health Technology?

Dr. RICHMOND. Yes; those are the issues, and that is why I in my introductory comments picked two examples, one of which has become outmoded, even demonstrated to have significant harmful effects, and that we are trying now to pull back.

We hope that again through our NIH consensus building exercises perhaps we can anticipate some of those problems before we introduce new drugs for example, and through other kinds of collaborative activities among our various agencies, try to identify those hazards in advance.

We are not so immodest as to say we are going to be 100-percent successful, because one cannot be clairvoyant about all of these things, but we do want to bring benefits when there is consensus that there may be benefits.

On the other hand, we can proceed more rapidly in other areas. In the measles example I cited we could not have raised the question about eliminating measles even as recently as 2 years ago. The rates were too high. We have now moved down to a level at which it becomes disfunctional to move along with the same kind of strategy that we have employed in the past. We now need the development of a new strategy that moves much more toward containment of outbreaks while maintaining the overall immunization effort.

We need reassessment particularly of some of the high cost kinds of technologies. End stage renal disease, because we are expending such large amounts of money, is an important one to look at. All of the issues were not aired. For example, I would hope that one of our forthcoming exercises would be not only the issue of home dialysis, but the whole matter of minimizing the development of end stage renal disease. We have consulted, through some of our NIH consensus building exercises, with nephrologists. Some of them would put much more resources into understanding more about causation and ultimately, hopefully, prevention, rather than putting so much of an investment into the therapeutic aspects. Now, we are not suggesting that is unimportant or that we should move much more actively in the direction of transplantation, which is not without hazards of its own. But these are the kinds of judgments that we would like to begin to make in a more formal way.

What I would like to suggest is that this indicates we have come through an historical process. Prior to World War II it really didn't make much difference; we had only four or five specific kinds of medical therapies. We had surgical therapy, but aside from liver extract, quinine and a few others, we had nothing specific.

Since World War II we have developed very potent preventive diagnostic and therapeutic armamentaria. We can no longer depend on the process we used to rely on, the text book writers arriving at some judgment and purveying it to practitioners in the health field. We do hope what we can undertake through the development of this Office is a very systematic review, that we can accelerate the process, and that we can enable all people working in the health field to work with greater critical capacities and skills and hopefully much greater effectiveness in terms of the care that patients receive.

What we are really talking about is maintaining the overall trend toward better health for Americans, but accelerating that trend.

Dr. WELLS. Thank you.

Dr. Murray?

Dr. MURRAY. I would like to sift out of the many questions and answers this morning, the questions of particular concern with respect to the Office of Health Technology.

Its functions have been described in two major ways. One is supplying a certain need in technology assessment and medical practice evaluation. Another description, however, mentions the Office of Health Care Technology as a management resource of some sort. It suggests coordinating.

I would like to ask for some specific response on how those two descriptions fit together, and what sort of particular function you envision for the Office of Health Technology as a management resource?

Dr. RICHMOND. I think the management part of it is not management for management's sake. The reason why we need an office at the level of the Assistant Secretary for Health is that there are many contributions to be made to technology assessment and transfer which come from various sources, all of our six PHS agencies, the extramural community, and from industry. All of these things feed in, and the reason why we need this office is not just to manage the enterprise but to draw on all of the resources, the knowledge base that comes from all of these sources, and to arrive at judgments that are more sound than those that evolve now in a rather random fashion.

Mr. MURRAY. Who would plan broad scale strategies of the package sort that, Mr. Scheuer was discussing with Mr. Derzon. He was searching for a package of measures, what he called a management program.

Who would construct a management program and present it to the Secretary or present it to the various actors or agencies that have to participate in such a broad program?

Dr. RICHMOND. I think there are various frames of reference. The chairman, I think, was talking about several. Some relate largely to the financing of health care in the incentive area, and there is

the whole category that relates to technological issues. They are inter-related very clearly.

We would have the Office of Health Technology assume the major responsibility for the technology assessment and transfer issues. There we have an intra-departmental and inter-Public Health Service committee that would provide some professional guidance and help to the director of that office. But also, as we indicated, there would be an advisory council, extramural people that would be essentially the policymaking body.

The overall matter of reimbursement issues and the financing of health care is a responsibility which the Health Care Financing Administration largely has at the present time, and which the Office of the Secretary as well as my office participates in. We try to help in the formulation of those policies, and largely the Health Care Financing Administration, the Office of the Secretary, and the Public Health Service collaborate.

Dr. MURRAY. Thank you, Dr. Richmond.

Mr. ALTHIUS. Mr. Secretary, what percentages of new technologies coming out do you envision this new office will actually be able to, or have a need to, really analyze thoroughly? I would imagine it will really be quite small.

Dr. RICHMOND. You are asking a very significant question and, of course, one that gets into the definition of technologies. There are many practices which emerge that are largely in the realm of state-of-the-art. That does not mean that this office would be oblivious to those if some——

Mr. ALTHIUS. Which raises a second question which I wanted to ask as well, and that is, at what stage in a technology development would you propose to analyze it? Can you generalize at all on that point? For instance, if the CAT scanners had been analyzed very early in their development, people could have come to the conclusion perhaps that their cost exceeded their use. However, there are many examples where they are truly cost-effective when we look at the situation today.

Dr. RICHMOND. To go to the latter part of your comment first, certainly if we had a number of the things in place at the time the CAT scanner was emerging that we now have in place, I think we could have anticipated many of the problems, although perhaps not all of them. We might have been able to introduce a more rational process. I am not using the term regulatory process, because not everything that is rational needs to be regulatory in the strict sense of the word.

So I think we could have done a lot.

Now I think your other question concerning the potentially large volume of issues which might come before us goes back to Dr. Perry's question about management function, and the response is that it is more than management. This office does not have to be the depository of all the skills. It is precisely because we have so many skills in the Agency, the community and the Nation more broadly that this office can draw on those, and as they arise they develop some process by which we can make recommendations concerning many of these that come along.

Now, I think it is the more major issues with potential large-scale impacts in terms of either quality of care—that is, safety or

efficacy kind of consideration—or financing implications that need to be elevated to these kinds of exercises, these candidate technologies that we were referring to earlier, so that I think we will have to develop a process by which we sort these out.

Also, we have not talked very much about this, but we would plan to draw very heavily on the extramural community through grants and contract processes, so that we would not anticipate that this office is going to have the resources within itself, but it goes beyond just managing the effort. That is, it has to be an informed kind of management that is clearly targeted at some very clear goals.

Mr. SCHEUER. Dr. Richmond, you and the whole panel have been very generous with your time and we very much appreciate it. The one question I have above all is where is this all going to be put together? It seems to me we have an urgent need for somebody at the mountaintop to look at the whole congeries of independent fiefdoms down there, each doing things that affect the choice, the development, the testing and the clinical use of technology.

Where is the leadership going to be for a look from the top of the mountain over the whole length and breadth of the whole care system, and looking at incentives to reduce costs, incentives to seek the lowest level of technology and costs and intensity of service appropriate to each patient?

Who is going to take the responsibility for designing and organizing and directing that study so that all of these disparate elements in HEW will be looked at to get some kind of holistic view as to how restructuring and refocusing and redesigning of the incentive and the reimbursement systems can be rational and planned? Where is the leadership going to come from?

Dr. RICHMOND. Mr. Chairman, certainly in the Public Health Service that responsibility rests in my office. While it is true we have six agencies, with all of the complexity that has been associated with growth in the field of health, I think we do have the capacity to bring all of that together. The establishment of the Office of Health Technology is one example. In fact, to manage that enterprise we cannot leave it to any one agency or have one agency try to provide the lead for another. That has to be at my office level.

Concerning many of the manpower issues and incentive issues which are related to the kinds of policy problems that you have discussed—that is, the overall health care system—I do have under me an Office for Health Policy Research and Statistics headed by Mrs. Ruth Hanft. She has the responsibility for trying to generate recommendations in those areas.

The Health Care Financing Administration, of course, has very important responsibilities in relationship to medicare and medicaid, which constitute a very significant expenditure of the total health dollar in the United States. Mr. Derzon has already indicated that they have generated some position papers on many issues. We collaborate with them. None of these papers go forward to the Secretary without them having an opportunity to comment on ours, and provide us with critical reviews, and we have the opportunity to do it with theirs.

I should also add we do have the benefit of people in the Office of the Assistant Secretary for Planning. In that office there is representation from the field of economics, in particular, so that we have their critique as well.

The ultimate synthesis is a collaborative one at the level of the Office of the Secretary. I can say that the Secretary has a deep interest in these issues, and as our recommendations come to him we will have a synthesis of this. I am sure in the not-too-distant future he will have occasion to be testifying on these many issues.

Mr. SCHEUER. In the meantime, could you send us down perhaps for inclusion in the report of this hearing these various memos and studies that you have just mentioned?

Dr. RICHMOND. Yes.

Mr. SCHEUER. When do you think you will have completed the study that you just discussed?

Dr. RICHMOND. There are some comprehensive studies that we can make available to you virtually immediately. The problem of synthesis, we would have completed by the first of the year.

Mr. SCHEUER. Very good. We will look forward to getting the studies that are available now and we will look forward to this further comprehensive oversight investigation after the first of the year. And we are very grateful to you all for your patience and tolerance.

Mr. SCHEUER. We will now hear from Dr. Joyce Lashof, Assistant Director of the Office of Technology Assessment, and Dr. David Banta, Health Program Manager.

We are very happy to have you here, albeit under a new heading, Dr. Lashof. You are a familiar face coming to us in unfamiliar guise, but it is the same sharp intelligence and we are very happy to have you here. Your statement will, of course, be printed in full at this point in the record, so perhaps you would like to chat with us informally and I am sure we will have some questions; and Dr. Banta, any time you feel the urge to intervene, please do so.

[The prepared statement of Dr. Joyce Lashof follows:]

STATEMENT OF

JOYCE C. LASHOF, M.D., ASSISTANT DIRECTOR
H. DAVID BANTA, M.D., HEALTH PROGRAM MANAGER
OFFICE OF TECHNOLOGY ASSESSMENT
CONGRESS OF THE UNITED STATES

BEFORE THE

SUBCOMMITTEE ON DOMESTIC AND INTERNATIONAL SCIENTIFIC
PLANNING, ANALYSIS, AND COOPERATION
COMMITTEE ON SCIENCE AND TECHNOLOGY
U. S. HOUSE OF REPRESENTATIVES

OCTOBER 6, 1978

Mr. Chairman and Members of the Subcommittee:

We are pleased to appear before you to describe the work of the Health Program of the Office of Technology Assessment. OTA is deeply involved in work related to medical technology and health care costs, the subject of these hearings. We understand that you are particularly interested in OTA's past and potential contributions to the analysis of the problems being considered in these hearings.

Science and its applications have had profound impacts -- both positive and negative -- on the quality of life. This impact is likely to continue and increase. It was assumed until the mid- to late-1960's that nearly all technology in the medical care sector was good and that added technology could only be beneficial. However, the levelling off in obvious improvements in health status, the appearance of serious side effects of some medical technologies, and the rapidly rising cost of health care have led us to begin to take a more balanced view of technology and the benefits derived from its use. We now recognize that the use of technology is not always desirable, may not be desirable for all patients under all circumstances, or may not be worth the costs.

Congressional concerns about technology in all fields led to the establishment of the Office of Technology Assessment in 1972. The statute gave OTA the assignment to "provide early indications of the probable beneficial and adverse impacts of the applications of technology." It also charged OTA to provide Congress with "competent, unbiased information concerning the physical, biological, economic, social and political effects of such applications." OTA's formation was stimulated by the need to assess the effects of technologies such as supersonic transport, anti-ballistic missiles, and the widespread use of pesticides. As society has become increasingly dependent on technology,

Congress found that it lacked a source of even-handed, authoritative technical information. The Executive Branch agencies often either promoted specific technologies or programs dealing with technologies. Technologists tended to over-emphasize the benefits of technology while minimizing difficulties and underestimating costs.

OTA's assignment is to look into the future, examine technologies whose benefits and risks are difficult to foresee, and present alternative policies for dealing with those future impacts. OTA programs cover a number of broad areas in addition to health and include transportation, energy, food, materials, telecommunications and oceans. OTA's multidisciplinary staff gives it the capability of dealing with issues that cut across traditional subject areas and agency jurisdictions. All studies attempt to look at technology from a global perspective. With a staff of only 130 and a budget authority for FY 1979 of $11.4 million, OTA must use its resources very wisely. This means, above all, working on issues that will have a major impact on the quality of life of future generations. It means choosing projects that will define opportunities for Congressional action. If OTA can stimulate Executive Branch agencies to become more involved in evaluations of technology, its limited funds will have a multiplier effect.

OTA uses consultants, contractors, and advisory panels for its studies. We can balance, for example, the optimism of the technologists, the interests of industry, and the concerns of public interest groups. By seeking outside help, OTA can tap the best experts in the country and avoid becoming an inbred, know-it-all agency. OTA's job is to integrate a broad range of information and opinion into un-biased, authoritative reports that will help Congress make choices on critical problems. OTA also seeks broad public participation in projects by including representatives of the general public on study panels.

All OTA assessments must be authorized by the 12-member Board of OTA, which is made up of 6 Senators and 6 Representatives, equally divided by party. Assessments can be requested by the Chairman of any Congressional Committee, by any Member of OTA's Board, or by the Director in consultation with the Board. Until this year, most requests for assessments have come from Committee Chairmen.

In the health area, OTA has published 6 reports. We will briefly describe each of these and will also make a few observations about how they may have been helpful to Congress and to others.

The first study, Drug Bioequivalence, was requested by the Senate Human Resources Committee and was actually the first published OTA report. The study was done in 1974, before OTA had a health program. OTA was asked if the existing technological capability could assure that drug products with the same physical and chemical composition would have comparable therapeutic effects, i.e. bioequivalence. The report concluded that current standards and regulatory practices do not insure bioequivalence of drug products. It included a series of recommendations designed to improve bioequivalence, or, at least, recognition as to when bioequivalence is important and when it is not. The report also recommended development of an official list of interchangeable drug products. The report was requested because of proposals to require generic prescribing of drugs in Federal medical care programs, and because of recognition on the part of Congress and Executive Branch agencies of the related problems. According to officials of the Food and Drug Administration, the report has had a very positive effect on both cost-containment and improved drug bioavailability. FDA implemented essentially all of the report's recommendations without further Congressional action.

The second study published by OTA was the first of three done under a

request from the Senate Human Resources Committee to "examine current Federal policies and existing medical practices to determine whether a reasonable amount of justification should be provided before costly new medical technologies and procedures are put into general use." Because the issues relating to medical technology are complex, the OTA health program advisory panel recommended dividing the subject into a series of discrete studies. The first study examined the development of medical technologies, and considered:

1) The need for assessing the potential social impacts of new medical technologies during the research-and-development process;

2) The kinds of questions that might be asked in such an assessment; and

3) By whom and at what point in the research-and-development process assessments could be conducted.

This study was titled Development of Medical Technology: Opportunities for Assessment, and was published in August, 1976. It demonstrated that many medical technologies do have profound social impacts. Nine case studies were prepared to illustrate the diverse nature of medical technologies, the complexity of technology development, and the variety of problems posed by technologies. A list of questions that could be used in technology assessment was developed and was used to illustrate other social impacts. The state of the art of technology assessment was reviewed and policy options were presented that discussed where technology assessment might be done fruitfully. This report has been widely quoted and cited. Indeed, in these hearings it was cited by Andrew Miller of the Hospital Corporation of America. The report led the National Institutes of Health (NIH) to discuss actively the subject of social impact assessment. When the Director of NIH established the Office of Medical Applications of Research (OMAR), social impact assessment was included as part of the charge. Finally, social impact assessment gained visibility from the report and was included as an area to study in House and Senate bills to

establish a new program to evaluate medical technology (H.R. 12584 and S. 2466).

The second report under that general request examined the computed tomography (CT) scanner. It was also requested separately by the Senate Committee on Finance in 1975. A preliminary report was completed in the fall of 1975 and was widely circulated. It helped stimulate and was a basis for the Institute of Medicine report on CT scanners. It was of particular help to planning agencies across the country that were attempting to deal with CT scanners. This experience, by the way, pointed out to us how critical technical assistance is to these planning agencies.

Reaction to the preliminary report convinced health program staff that the CT scanner was worthy of an in-depth study concerning its policy implications. Federal policies, particularly those of the Department of HEW, were reviewed in detail. The final report was published in August, 1978. In brief, the report found that the CT scanner is an exciting but expensive technological development. The efficacy and cost-effectiveness of CT scanners have not been carefully evaluated. Nonetheless, the United States had more than 900 scanners by the end of 1977. On a per capita basis, that is significantly more than any other country in the world. Health planning agencies and PSROs have not been effective either in controlling the diffusion of CT scanners or in channelling their use to improve their effectiveness. Distribution is uneven. While large potential user institutions do not have a scanner, 17 percent of them are in private offices where their availability is limited. Most importantly, the report found that the Federal government and private insurors, by their reimbursement policies have, in effect, assumed an open-ended commitment to finance CT head scanner services. Reimbursement mechanisms exert little pressure to perform services, such as CT scans, efficiently. Furthermore, there is little incentive to choose among alternative technologies in the context of

prevailing financing methods. Present methods tend to promote the additional use of technologies, even if the results are duplicative. The report presented a series of policy options that address these problems, including assuring more careful evaluation of new technologies, strengthening Federal regulatory programs, and changing incentives in Medicare and Medicaid to encourage the wise use of technology. On the last point, the report pointed out that the payment system could establish rates based on efficiency. The report also pointed out possible changes in the reimbursement system, such as prospective reimbursement, to counter the perverse incentives presently built into Medicare and Medicaid.

It is too early to judge the impact of this report. Certainly, material on the CT scanner such as the OTA draft report helped stimulate bills to establish new programs for the evaluation of medical technology. The facts presented in early drafts and in the final report convinced many people of the necessity to include physician offices under health planning authorities. Other suggestions in the report are being actively discussed by Congressional staff and by members of the Department of HEW.

Finally, this September, OTA published Assessing the Efficacy and Safety of Medical Technology, the final report relating to the Senate Human Resources Committee request. Mr. Clyde Behney described that report on September 26 in his testimony before this Subcommittee, so we will not describe it again here. Staff on several Committees of the Congress have stated that the report convinced them of the need for a program to evaluate the efficacy and safety of medical and surgical procedures. In part, it seems apparent that the early drafts of the report supported the development of H.R. 12584 and S. 2466, and were used extensively in the DHEW Health Technology Management study.

OTA has also worked in the area of health data systems. In 1975, the Senate Human Resources Committee requested a general study of such systems,

including medical record systems. In 1977, OTA published the first result of that study, Policy Implications of Medical Information Systems. The study noted that traditional handwritten medical records are not adequate for the many demands placed on them by clinicians, administrators, third-party payers, planners, and regulators, and that computer technology offers a possible solution to inadequacies of medical records. The report examined three existing computer-based medical record systems, and concluded that with appropriate development, such computer-based systems can improve patient care, support clinical decisionmaking, facilitate assessments of quality, and produce better data for use in health data systems, planning, and epidemiological research. The report pointed out various ways to encourage additional development and diffusion of computer-based medical information systems. The report was featured in hearings before this Subcommittee last May, so we will not go into more detail. We will say, however, that the report has been widely circulated and discussed and has helped lead to a mandate in proposed legislation (S. 2460) for research, evaluations, and demonstrations on "the uses of computer science in health services delivery and medical information systems."

Under the same request, the health program is presently completing two projects: a review of legislatively mandated health data systems and an examination of current policy mechanisms for the coordination of Federal statistical activities. Existing data systems have many gaps and duplications, and many of these problems result from inadequate coordination of the numerous activities of Federal agencies.

Finally, at the request of the Senate Committee on Human Resources, the health program did a study entitled Cancer Testing Technology and Saccharin. The study was requested because of the decision of the Food and Drug Administration decision to ban saccharin. OTA was asked to assess the

methodologies for testing carcinogenicity, the potential risks and benefits from saccharin consumption, and the potential availability of alternative artificial sweeteners. The report reviewed the studies of carcinogenicity of saccharin and concluded that it is a carcinogen with the potential to cause cancer in humans. The report also concluded that claimed health benefits from saccharin use have not been demonstrated. The study was praised for its objectivity and contributed to the Congressional decision to postpone the ban on saccharin, rather than amending the Delaney clause of the Food and Drug Act.

In addition to these formal studies, the health program has analyzed a variety of problems and has the capability to expand some of this work into formal studies. Most recently, background studies on the use of computers in assessing physician competence and of the cost-effectiveness of pneumococcal vaccine are being conducted.

Thus, the health program of OTA has done both long-term studies of important generic issues such as medical technology development and evaluation, and short-term studies of specific issues of immediate interest to the Congress, such as the carcinogenicity of saccharin. To be most effective OTA should anticipate problems, so that analytic work can be available when a policy issue emerges. Such anticipation occurred in the area of evaluation of medical technology. And as we will describe shortly, OTA is moving aggressively to improve its ability to anticipate problems. However, OTA must also continue to do studies of immediate importance to Congress. In the case of saccharin, the study was completed two months after the Board voted that it should be conducted. The ability to respond quickly is one of the strengths of OTA. Within the health program, we now have experienced and dedicated staff members, who are familiar with the Congress and Federal health programs and able to develop a study addressed to a given topic, identify outside authorities to help

in the study, and move to produce an end-product in a timely fashion. OTA is ready to work closely with Congressional Committees and Sub-Committees to meet their needs and to assure that the immediate legislative agenda has been considered.

However, to fulfill its Congressional mandate of anticipating the future and looking at issues comprehensively, OTA must do what Congress is not well organized to do and normally cannot do itself. That is, OTA needs to step back from the immediate and look at those issues and technological developments which will have their main impact five or ten years from now. OTA must identify generic issues that cut across Committee jurisdictions and that are dealt with by many different programs in the Executive Branch.

OTA is moving aggressively to improve its ability to anticipate problems. OTA has developed a priority list for future studies. When Governor Russell Peterson became Director of OTA early in 1978, he directed OTA staff to solicit suggestions for technology assessments from many sources and to devise a system whereby these suggestions and others could be compared and ranked according to explicit criteria. Thousands of suggestions for projects were received. Congressional input was sought, as was broad public input. As the list was developed and changed, it was distributed to many groups and individuals, including OTA advisory groups. At the present time, the list has 30 potential projects, five of which fall within the health program. (The latest version of the list is attached.) The top priorities on the list in the health area are Health Promotion and Disease Prevention, and Cost-Effectiveness of Medical Technologies. Because OTA has been working on the issue of evaluating usefulness of medical technologies for several years and has expertise in the second area, we decided to seek Congressional Board approval for the Cost-Effectiveness project first. It was approved by the Board on October 3,

1978. We plan to take the Health Promotion and Disease Prevention project to the Board in January, 1979.

In each of these generic areas, OTA will seek input from interested Congressional Committees. These hearings have indicated that this Subcommittee is very interested in the incentives in the existing health care delivery system and how those could be changed to incorporate cost-effectiveness considerations. We will try to incorporate such concerns in the study. Other Committees are more interested in the cost-effectiveness of specific medical technologies. We will do some case studies and a few more detailed studies to accommodate such interests. One Committee is more interested in the generic issue of cost-effectiveness -- what is it, how many have been done, what the results have been, what if any difference the results have made to public policy. By doing a comprehensive study of cost-effectiveness, we hope to accommodate many interests. We also will rely on Congressional Committees for advice on which aspects need more attention to be most useful.

The priority-setting exercise will continue and the list will be periodically up-dated. For example, on the present list one item is "Prospects for Increased Longevity," including societal impacts of such an increase. This is certainly an important subject and deserves attention. When the cost-effectiveness project is completed, the longevity area may be the highest priority health project. It may then be carried out, or another problem may emerge that has greater significance.

There are also projects on the priority list that cut across program lines. For example, OTA is beginning a study of regulation and technological innovation. The study will deal with regulation generically, but will include examples and cases from the health area. Another project deals with the impact of nuclear war, and part of that project will involve the diseases and health

conditions that would be expected to result from use of nuclear weapons. A study has just been initiated on applied genetics and will include human applications, but will consider plant and animal genetics as well. An assessment is being planned on technology and the developing world, in part to determine which beneficial technologies can be readily transferred from this country to others. And finally, OTA is planning a project to examine the world population problem and to delineate options for dealing with it.

In selecting priorities, OTA uses criteria in three general categories: topical factors, client-related factors, and organizational factors. In the first category of criteria factors, questions are raised concerning the number of people affected, the impact on quality of life, the impact on the broader society and on future generations, and so forth. Among the second category of factors, OTA asks questions regarding the likelihood of Congressional use, the importance to national priorities and needs, and the possibility of its impacting key decisions while those decisions are being made. And in the third category of factors, OTA asks what it can uniquely contribute and whether the project is doable and can be completed in a reasonable time period.

We expect that by using the priority list and by seeking Congressional input, OTA will be able to satisfy its legislative mandate. To fulfill its mandate, OTA must do more than respond to Congressional requests. It must try to anticipate emerging problems and opportunities and help to make Congress aware of them. We are mindful, of course, that we must be responsive to the immediate concerns of the Congress if assessment reports are to be utilized.

OTA PRIORITY LIST

(Revised September 16, 1978)

		Movement since 8/21/78 Ranking
A	NATIONAL WATER SUPPLY AND DEMAND	A → A
	ALTERNATIVE GLOBAL FOOD FUTURES	A → A
	HEALTH PROMOTION AND DISEASE PREVENTION	A → A
	IMPACT OF CHANGING TELECOMMUNICATIONS POLICY	B → A
	TECHNOLOGY AND WORLD POPULATION	B → A
B	REGULATIONS AND TECHNOLOGICAL INNOVATION (Health/Environment/Safety)	A → B
	IMPACTS OF APPLIED GENETICS	B → B
	COST EFFECTIVENESS OF MEDICAL TECHNOLOGIES	C → B
	IMPACT OF NUCLEAR WAR	B → B
	PRODUCTIVITY OF U.S. CROPLANDS, FORESTS AND WETLANDS	A → B
C	TECHNOLOGY AND THE DEVELOPING WORLD--MEETING BASIC HUMAN NEEDS	D → C
	PEACE TECHNOLOGY	C → C
	FUTURE OF MILITARY EQUIPMENT	C → C
	DESIGNING FOR CONSERVATION OF MATERIALS	D → C
	IMPACT OF MICROPROCESSING ON SOCIETY	E → C
D	UTILIZATION OF EXTRATERRESTRIAL SPACE	E → D
	MOVEMENT OF GOODS	D → D
	WEATHER AND CLIMATE TECHNOLOGY	C → D
	TECHNOLOGY AND DECENTRALIZATION	E → D
	CONTROLLED THERMONUCLEAR FUSION	F → D
E	POTENTIAL FOR ADVANCED AIR TRANSPORT	D → E
	POTENTIAL ECONOMIC IMPACTS OF FEDERAL R&D	B → E
	PROSPECTS FOR INCREASED LONGEVITY	F → E
	PRESCRIPTION DRUG USE	F → E
	TECHNOLOGY AND MENTAL HEALTH	F → E
F	FOREST RESOURCE TECHNOLOGIES	F → F
	ENERGY EFFICIENCY IN INDUSTRY	F → F
	DEEP OCEAN MINERALS DEVELOPMENT	D → F
	ROLE OF TECHNOLOGY IN MEETING HOUSING NEEDS	E → F
	OCEAN WASTE DISPOSAL	E → F

TESTIMONY OF JOYCE LASHOF, ASSISTANT DIRECTOR, AND DAVID BANTA, HEALTH PROGRAM MANAGER, OFFICE OF TECHNOLOGY ASSESSMENT

Dr. LASHOF. Thank you very much, Congressman. It is a pleasure to be back in a different kind of role and discussing a different issue, although part of this morning's discussion was fairly reminiscent of the last time I was before you.

Mr. SCHEUER. Indeed, the more things change the more they remain the same.

Dr. LASHOF. What we would like to do this morning, since, our statement has already been submitted for the record, is to briefly give some of the history of the Office of Technology Assessment. I would like to ask Dr. Banta to describe briefly the first six studies that have been produced in the health area, then I will briefly sum up some of our ideas of things we would like to see accomplished over the next few years. And we will make it very short.

The Office of Technology Assessment was set up by Congress because of the growing concern of Congress for the impact of technology, all types of technology, in all the fields; the impacts of these technologies on our society, both beneficial and negative; and the need for Congress to have an arm that could independently assess in a more objective and unbiased way, if possible, and get some balance between the advocates of technologies and detractors of technologies.

To quote briefly from the OTA legislation, it was "to provide early indications of probable beneficial and adverse impacts of the applications of technology." It also charged OTA to provide Congress with "competent, unbiased information concerning the physical, biological, economic, social, and political effects of such applications."

That is a rather large charge and obviously one that OTA cannot apply to every technology that comes about.

In the health area, the effort has been to take a look at some key technologies and some key issues around technology, and then in doing these studies, draw some policy implications.

One more word about the fact that in the Office of Technology Assessment we have programs that cross a number of areas, and health is just one. Food, world population—which I know you are interested in—are others. In addition we have programs in energy, transportation, oceans, and research and development. This does give us an opportunity to bring together a multidisciplinary staff from all of these fields and to bring those efforts together in some of the crosscutting issues. Thus we can call upon some of the economists that may be part of the energy program to aid us in looking at some of the issues in the health program and vice versa. We in the health program hope to be able to interact with other staff in looking at problems in energy, et cetera.

I will ask Dr. Banta to describe some of the early studies, and I will come back and give you a little bit of a projection.

Dr. BANTA. Thank you. We have done, as Dr. Lashof said, six studies in the health area. I would say five of those have great applicability to these hearings and could be fairly timely as background for the hearings. This has been recognized in your invitation to us to present our efficacy and safety report in an earlier

part of these hearings. [Testimony of Clyde Behny and of Lester Breslow.]

Let me just run through what the six reports are. The first report was on drug bioequivalence and included a series of recommendations designed to improve bioequivalence. The officials of the Food and Drug Administration have stated that the report has had a very positive effect on cost containment and on improved drug bioavailability measures. The second report had to do with the development of medical technology and with social impact assessment, including the financial cost of medical technology. So again, it has a great deal of applicability in these hearings. In that report, the state-of-the-art of technology assessment was reviewed and policy options were presented, including a discussion of where technology assessment could be done more fruitfully.

Social impact assessment gained visibility from that report, and I think it has had quite a bit of impact both in HEW on the establishment of the Office of Medical Applications Research at NIH, and in legislation, where it was included in H.R. 12584 and S. 2466 as an important function.

The third report had to do with CAT scanners and we have discussed that somewhat already in these hearings. Just to sum up some of the findings of that report, we found that CAT scanners are certainly an exciting but also expensive technological development, that the efficacy and cost-effectiveness of scanners have not been carefully evaluated, and that health planning agencies and PSRO's had not been effective either in controlling the diffusion of CAT scanners or channeling their use to improve effectiveness.

We found about 17 percent of the scanners are in private office settings where availability to the broader community is limited. Most importantly, the report found that the Federal Government and private insurers by their reimbursement policies have in effect assumed an openended commitment to fund scanning services, particularly head-scanning services.

The report presented a series of policy options which I think are of interest to these hearings, including some proposed changes in the incentive system under medicare and medicaid.

The fourth report in that series concerns the assessment of the efficacy and safety of medical technology, and since that has been discussed in these hearings I will not go into it further at this time.

We also had a report on policy implications of medical information systems which you reviewed in hearings last May, so again I will pass quickly over that. And finally——

Mr. SCHEUER. When did you produce that report?

Dr. BANTA. In 1977.

Finally, the report on cancer testing and saccharin which the Human Resources Committee demanded as an aid in dealing with Congress problems in deciding what to do about saccharin.

Just one final word, in part to correct some confusion about our role and the facts concerning some of these studies. You asked, Mr. Chairman, if in looking at these technologies, we have examined cost-effectiveness of the technologies. We have examined the effectiveness of a variety of technologies and where possible, where there are estimates, or where we have been able to do our own estimates, we have also examined the cost of those technologies.

We have done, in these various reports, case studies of about 26 or 27 separate specific medical technologies. To give you a sense of their contribution to the rising cost of medical care, automated clinic laboratory testing now costs about $15 billion a year; X-ray services almost $5 billion; CAT scanning in 1976, about $280 million; skull X-rays—which were mentioned already today by Dr. Novitch—$221 million; electronic fetal monitoring, about $400 million; coronary bypass surgery, about $1 billion; tonsillectomy, $500 million; appendectomy, $350 million; and hysterectomy, more than $1 billion.

Now I will turn the discussion back to Dr. Lashof to tell you where we are hoping to go in the future.

Dr. Lashof. Let me say, as we try to look at these, that the resources of OTA are obviously quite limited. The total budget for the organization is $11 million, with a staff ceiling of 130 people. That is for all the programs. Clearly, then, we have to set some priorities, pick some big overriding issues and try to draw policy implications for the Congress from those rather than to try to undertake detailed assessments of each one of the technologies.

And although as part of our studies we do case reports on the list that Dr. Banta just gave you, which are essentially cases that were cited as part of bigger studies, we do not purport that even those were done in the sense of a total and comprehensive technology assessment of the type that was discussed this morning in the presentation of what the responsibilities of an Office of Health Technology within HEW ought to be.

But we are moving as aggressively as we can to anticipate problems and to pick those kinds of issues which are coming on the horizon, and to step back a little bit from the day-to-day pressures and take that longer range look that we think Congress needs.

When Governor Peterson took over the directorship of OTA early in 1978 he directed the staff to solicit suggestions for technology assessment from many sources and to devise a system where those suggestions could be compared and ranked according to explicit criteria.

He made this request quite broadly throughout the country, and he received recommendations of several thousand issues that one ought to take a look at. The staff culled thousands down initially to about 200 and again reviewed them, and they were reviewed by congressional committees and experts around the country, and at the present moment we have a potential priority list of about 30 projects. In all the areas we hope this will be a dynamic list, and as projects are approved by our congressional board, they move off the priority list and new ones will be added on. So we have a holding list of about 30, and that will give you an idea of things we hope to look at.

Mr. Scheuer. You cannot do it all, that is perfectly obvious. You could not handle it.

Is there any way through some kind of seminar approach or series of indoctrination or training sessions you could sort of reprogram staff people and of course Members of Congress to look at problems in your frame of reference, to get them to analyze the problems more systematically themselves, as if they were extensions of the OTA. In other words, we have 10,000 members of staff

around here, if we could sort of impregnate them with the seed of a different approach in looking at problems. Do you have a real multiplier effect working for you?

Dr. LASHOF. We certainly want to do that, and it is our hope—I do not think we have thought specifically of formal seminars for staff, but it is certainly something we could explore with Congress and our board and the staff of the various committees. We are trying, through the reports and through our work with the staff in the process of the reports, to give them the kind of approach that OTA has used. We have been doing that in an informal way. As we are developing the priority list and looking at the issues we have been working with the staffs of the key committees, and we do invite the staff to participate in the panel meetings and the discussions that are part of the assessment process, so that even long before a report may actually come out it often includes some of the thinking and some of the work of the committees that we may have been working with along the way.

I think that is a very important goal. The need to institutionalize that and develop a more formal structure, I think, is an excellent suggestion, and I certainly will discuss that with Governor Peterson.

Mr. SCHEUER. I can see you having a training session of 1 week, 2, 3, 4 weeks that would be a continuous thing, and committee chairmen would actually assign, on a sort of revolving door basis, their key staff people to take this orientation course one after the other during the course of the year and over a couple of years—let's say it is a 1-week course, I would think you could really hit the highlights of this new way of analyzing and evaluating projects and programs.

You could get, I would think, a clear preponderance of the key staff people over the year through this indoctrination, orientation, whatever you call it. Over the course of a couple of years you would have several thousand people at a top staff level who have been exposed to the kind of systematic analysis that you apply to your projects and program.

Dr. BANTA. To add to what Dr. Lashof said, we are very mindful of our very small resources in this vast area. So generally speaking, we try to pick a generic policy issue, such as efficacy and safety. And I think it is fair to say that our analysis of that problem, which goes back more than a year, had quite an impact on the health care technology task force in HEW which led to the Office of Health Technology.

It is still early in its implementation. We don't know how effective it will be in the long run. But if it does work, I think we can take some credit for a multiplier effect in getting technology evaluation institutionalized within HEW. That would be our goal, among others.

Dr. LASHOF. I think if I briefly mentioned some of the priorities we are going to look at, you will see how that will apply, because the next priority for the health program that was just approved by the board earlier this week is a study of cost effectiveness.

Now, in that study we will be looking at methodology for judging cost effectiveness, as a technology for evaluating things, and what we will try to do is to identify those kinds of procedures and

technologies of the other type that are amenable to cost effectiveness.

What do we know about cost effectiveness evaluation? Is it a technology that can be applied widely? What are the pros and cons? What are its advantages and disadvantages? And which are the things that it is most applicable to?

In the process, we will pick some technologies and do cost effectiveness and we will try to identify the problems in using that technique, and we will then try to go on to the question you are asking this morning: How do we then apply the knowledge we gain? What are the policy options open to executive agencies? What are the policy options open to Congress to using cost effectiveness in setting priorities and in passing legislation and restructuring reimbursement systems, and the whole gamut?

It is a big order. And it sounds like we are just taking a technology. But the implications of looking at that technology are quite broad.

Mr. SCHEUER. You bet they are.

When will this study be finished?

Dr. LASHOF. We just got approval this week and we are just starting; it is geared to taking about a year to do it. We will have some interim reports along the way as we do individual case studies. We will be working with staff and will be able to report on where we are going, but I am optimistically hoping to complete the whole study in 18 months.

Dr. BANTA. As Dr. Lashof said, we will have interim reports. We have signed a contract just this week with a very good economist to review the entire published literature on the cost effectiveness in the medical area and hope to have that report available in February or March, not only for others, but for our own expert panel's deliberation.

Mr. SCHEUER. That is very helpful, and that is very encouraging.

Dr. BANTA. We have involved the Congressional Budget Office in the planning of this study. We have not actually talked directly to Alice Rivlin, but Paul Ginsberg, the head of the health group has been involved in this, and we plan to keep closely in touch.

Mr. SCHEUER. I would think you would enjoy chatting with her. I think she would be interested in making a contribution, if she knew that kind of activity were going on, because she and Bill, as I said, were two early pioneers in the whole business of applying cost-benefit analysis to the HEW mandate, so to speak.

Dr. LASHOF. I thank you for that, and we will certainly follow up. I think we will also talk with them on another study that we project to try to prepare for board approval in January and then undertake sometime later, where we do hope to take a look at some of the key issues in the prevention and health promotion. And in looking at that, we will pick some specific areas that we think present problems, such as carcinogens in the workplace, and take an overview look. But one of the things I think we also need to look at in there is if one gets all of this information, how does one reallocate resources around developing prevention programs and away from others?

If we have limited resources, and there is a cap, whether it be on our budget or on a hospital, then how do you use those funds

effectively? Much of the discussion this morning talked about our cost reimbursement system being an open ended one. And how do you get control on that? Our budgetmaking process is not a simple one either. And in the sense of medicare and medicaid, it is open ended because of the reimbursement system they use. Congress being able to write a budget, has to fill that budget, and then what is left over goes to everything else.

Now, how are we going to reverse that? Can we reverse it only by changing the reimbursement system? Or even within the reimbursement system, can we look at our own methodology for allocation within Congress? And can we offer recommendations to you on that regard? We will make an effort.

Mr. SCHEUER. I am sure you can, and I am sure that would be helpful to a degree, but I hope you will go beyond that to looking at the very essence of the reimbursement system as a part of the problem.

Dr. LASHOF. Yes, certainly in the cost-effectiveness studies we will look at what impact the reimbursement system might have or what changes in it might impact on the utilization of cost-effectiveness.

I think in the prevention area we certainly will be looking at, if you are going to improve prevention, what are some of the changes that you will need in the superstructure and the infrastructure of the health care system to implement those, and where and how does the reimbursement system impact. We hope to look at those kinds of issues under each of the studies we undertake.

Mr. SCHEUER. That is very encouraging, Dr. Lashof. I can't think of a single element of the health care system that is in more need of study in terms of how we get cost-effective preventive care out of our system than the reimbursement structure. I can't think of a more disfunctional element in our health care system that is more destabilizing and more productive of wanton waste and overutilization and broad misuse and everything else than the single fact of the reimbursement structure.

So your words are encouraging.

I can understand that this kind of a study would take 18 months, and I don't think that is an unreasonable time frame. From our point of view, however, we are going to be considering important pieces of legislation before the end of the 18 months, like the hospital cost containment bill, the health services research and health technology bill, and probably some kind of a proposal for national health care that the President seems to be planning to send up to us, and it would be very helpful to us in our scrutiny of those bills if we can have some kind of interim input from you as you are proceeding.

Dr. LASHOF. We will be happy to work with your staff and give you answers as we go along. I would emphasize we are an arm of Congress, and we are here to try to serve and be as responsive as we can, but we cannot do short turn-around staff work. On the other hand, everything we are working on, we can share, and we can give you our best informed judgment, and we will be happy to talk at any point.

Mr. SCHEUER. And I hope, in addition to the staff of this DISPAC Subcommittee of the Committee on Science and Technology, that

you will be doing the same thing and sharing the same inputs with the members and staff of Paul Rogers' Health Subcommittee of the Interstate and Foreign Commerce Committee, as well as the Ways and Means Health Subcommittee.

Dr. LASHOF. Director Peterson has been scheduling a series of meetings with the senior staff people of all the major committees that we would relate to, and we have met with them and tried to explain the office, tried to introduce them to our people in the various areas and to make ourselves more known than apparently OTA has been in the past so we can serve that role with all these committees. We are systematically going from committee to committee and meeting with staff.

Dr. BANTA. In the case of the cost-effectiveness study, we had a specific request for the kind of study we propose from the Senate Human Resources Committee signed by Senators Williams, Javits, Kennedy, and Schweiker, and we had a request from the Senate Finance Committee on the cost-effectiveness of some specific technologies they were particularly interested in, signed by Senator Talmadge. We also have a letter from the House Interstate and Foreign Commerce Committee, which has asked for some help with cost containment. Committee staff have said this is a piece of what they would be very interested in.

Mr. SCHEUER. How about the Ways and Means Health Subcommittee?

Dr. BANTA. The staff people on Ways and Means have indicated interest. They have not made a formal——

Mr. SCHEUER. I hope that once you have completed some kind of orientation with staff, that you will offer this opportunity to Members. The Library of Congress has a very interesting series of evening seminars that they offer to Members of Congress. They go from 6:30 to 9 or 9:30 on a whole variety of subjects, energy and environment, everything, and it seems to me that some kind of a pattern like that could be worked out. And it would be very helpful to the Members, especially early in the legislative session, January, February, March, and April, before a great deal of the legislation gets cranked into the pipeline, and the calendar isn't quite so full as it gets to be late in the session, and especially in the second year.

So I would think the first 2 or 3 months of next year would be a time when Members would have some free time and would benefit greatly from the kind of knowledge and perceptions that you already are passing on to the staff.

Dr. LASHOF. Very good. We will be happy to look into that.

Mr. SCHEUER. Thank you very, very much. Thank you for your patience and your very fine testimony.

The committee is adjourned.

[Whereupon, at 1:40 p.m., the subcommittee adjourned, to reconvene subject to the call of the Chair.]

APPENDIX

Additional Material for the Record

Technicon Corp.,
October 12, 1978.

Hon. James H. Scheuer,
U.S. House of Representatives,
Washington, D.C.

Dear Congressman Scheuer: It was indeed a pleasure to have had the opportunity to appear before your subcommittee. You and your staff raised some very interesting questions which I pondered during my recent trip to Japan and Australia. I would like to comment on a couple of them in addition to forwarding the materials you requested for the official record.

First, I want to say a word or two about uniform accounting and its relationship to a well developed information system. Uniform accounting has to do with classifying and aggregating financial information in the same fashion in every hospital. Once the classifications and aggregations are decided, they can easily be incorporated into the information system, and every financial entry can automatically be handled in the same way, everywhere. The software associated with the system can assure this. As a result, I consider the achievement of uniform accounting or uniform reporting a simple matter, once its dimensions are established and a proper information system installed.

I would like also to add a few comments about the matter raised by Dr. Wells related to the view of some that lowering the cost per unit of laboratory services results in an increase in total costs because of a correspondent increase in volume. It is true that costs have risen and volume has increased. It is assumed, therefore, that the increased volume of more effectively performed services had been the cause of the cost increase. I am convinced that the conclusion is false, by virtue of the data from Montefiore Hospital cited in my testimony.

The proper analysis of the cost of laboratory services requires the following steps:

(1) Determination of the cost of a given volume of laboratory services before automation.

(2) Determination of the cost of the same volume of laboratory services after automation.

(3) Determination of the cost of the increased volume of the automated services that follow automation.

(4) Determination of the high mark-up, i.e., price versus cost on laboratory services that follow automation.

(5) Determination of the charges for new laboratory services added after automation and of the charges for added volume of non-automated services that are offered.

(6) Determination of the benefits, i.e., more rapid and accurate diagnosis, treatment and discharge, better results from increased accuracies and completeness that follow from automation of laboratory results.

An unbiased investigation along the lines of the six steps I have outlined would lay to rest, I believe, some of the factitious conclusions now reached about laboratory automation.

You asked me a very thought-provoking question as to my opinion of the bidding procedures such as was sought for medical clinical laboratory procedures for the City of New York. If you will remember, I asked for a little time to study my response to this question. The advantages, as I see them, are:

(1) It would stimulate competition and may produce a lower price based on a large volume of services.

(2) With the small number of laboratories under the program, it would allow close scrutiny of the laboratories used by the government thus allowing greater assurance of quality for Medicaid beneficiaries.

(3) It would allow the program simply to identify places where Medicaid beneficiaries should obtain laboratory services.

However, I believe that should this procedure be generally adopted it might have a negative effect on the quality of health care. It is important, and perhaps essential, that tertiary care hospitals provide in-house laboratory services. Time in providing laboratory answers becomes an important ingredient in the quality of services, particularly for the patient in the emergency room, recovery room, intensive care unit, etc.

I do not believe it would be palatable to most tertiary care hospitals to send out their laboratory work. Further, I am afraid that the savings achieved would not be

truly significant. Many of the costs would remain with the hospital even if the actual testing were withdrawn to a central facility. These include drawing the sample, collection of samples, separation of samples, reporting results, recording results, and administering this process. Based on a study of 66 hospitals (attached) these figures represent between 35 and 40 percent of the total pathology laboratory direct costs. When the remainder of the direct costs—those associated with actual testing—are compared to the cost of purchasing the service, we find the independent laboratory changes are usually less than 10 percent lower than the hospital laboratory costs. This doesn't appear to be a significant saving, particularly when quality of care can be so adversely affected.

Might we suggest instead market incentives like those present in other competitive markets. Because third party payers play such an important role in health services, especially hospital services, and reimbursement is a key to the process, the process has to be different for in-patients and out-patients. In-patients do not have a choice of laboratories from which they obtain services, but out-patients will tend to reject overpriced laboratory services in favor of those that are reasonably priced, just as for other products, if the out-patient must pay the difference in price. Thus for out-patient laboratory services, third party payers could establish the lowest price at which a laboratory service is reasonably obtainable and pay that price as a benefit. If a patient obtained the service at the lowest price location, he would pay nothing. If the patient obtained the service for his convenience at a higher priced location, the patient would be required to pay the full price differential. Patients should be given information as to the places where the price is fully covered.

The government's regulatory role would be minimum under this procedure. For in-patients, laboratory services should be reimbursed at the lowest price reasonable given the nature of the institution. If the hospital runs an inefficient laboratory, the hospital should be forced to absorb the cost of its inefficiency.

You asked me for a list of hospitals using the Technicon Medical Information System. Please find such a list attached, along with names of individuals who can be contacted.

You asked what reimbursement incentives we might suggest to achieve lower costs and prices. As you know, some 90 percent of in-patient care is paid for by third parties. These third parties should base their hospital reimbursement on what it would cost an efficient hospital to produce the services provided. There are several problems in installing such a procedure.

First, we would not wish to be too abrupt in applying it because we do not wish to force bankruptcy of many hospitals, but rather to induce them to change their inefficient ways. Therefore, reimbursement should be set to give hospitals an attainable goal for the following period with a gradual tightening up process occurring year by year. Hospitals that fail to comply should be penalized by holding back funds that permits modernization and growth. Hospitals that are efficient should be rewarded by allowing them funds to expand their capacities or, in the case of investor owned facilities, to provide a profit to their owners. Most hospitals are nonprofit. However, an improvement and expansion of service is an important motivating force to them.

A further incentive to efficiency might be provided through paying incentive bonuses to employees for excellence in performing service at lower cost.

The second problem with general incentive reimbursement is the technical problem of determining the cost of efficient performance. The Talmadge Bill has this determination as its objective and its sponsors appear to have concluded that their objective could not be carried out in full at this time, so that they propose applying the Bill only to routine services with a number of exclusions at the outset. We recommended a full scale effort to develop ways to carry out the needed determination of the cost of efficient performance, taking into account the various mixes of hospital product—between patient care and teaching and within patient care, depending on the characteristics of the patient as well as other factors. A number of such factors need to be taken into account in determining the cost of efficient performance including laboratory costs and energy costs in the area. Determining the cost of efficient production is largely a matter of measuring what comparable hospitals have been able to accomplish. The age of the plant and the degree of modernization affect whether hospitals are comparable. This cost estimation task is difficult and creates a gap between the theory on what should be done and what can be done now. However, the gap only means that we should move quickly to remedy the deficit in our knowledge, not that we should give up or that we should use a reimbursement approach full of inequities in order to obtain a fast cut in government expenditures.

You asked what ideas we might have to make it easier for hospitals to acquire cost containing technology. We have two suggestions in this regard:

(1) Federal funds to provide interest-free loans. Such loans should only be made where there is a clear repayment path out of savings.

(2) Front-end money for cost containing technology. The approach taken to help in capital investment in most enterprises is to allow an investment tax credit and to allow accelerated depreciation. The former is not applicable in the case of non-profit organizations, but the latter offers real possibilities, if the capital investment in cost reducing equipment could be written off rapidly, or even expensed, rather than capitalized. This is particularly true if the expenses are not subject to the reimbursement limits applied by Medicaid and some standard rate review programs. Significant aid to investment in such devices would be provided.

In other words, I am suggesting an aid to investment in cost reducing technology in the health field similar to that available in other industries. I am suggesting that more nearly analagous provision be made. If reimbursement processes in the planning program exert pressure to reduce costs and funds are available to make sure that would produce the result that is sought we would have completed the circuit. Now there are beginning to be pressures to reduce costs but no help is provided toward obtaining the objective.

Once again, I want to express my appreciation for allowing me to appear. It is encouraging that Congressional committees are making investigations such as yours, and I believe in the long run can have a profound effect on our health care system.

On a personal note, it is indeed encouraging to me to discover how knowledgeable and perceptive you are in this field. Please, for the sake of all of us, keep up this work—8-plus percent of the GNP deserves the effort.

With many thanks again for the opportunity, I am,

Sincerely,

EDWIN C. WHITEHEAD.

El Camino Hospital, 2500 Grant Road, Mountain View, Calif. 94042, telephone (415) 968-8111. Administrator: Mr. R. Edwin Hawkins—Contract Date: August 9, 1974 (renewal)—fully installed.

Ralph K. Davies Medical Center, Castro and Duboce Streets, San Franciso, Calif. 94114, telephone (415) 565-6779. President: Mr. George D. Manardo—Contract Date: September 1, 1972—fully installed.

Maine Medical Center, 22 Bramhall Street, Portland, Maine 04102, telephone (207) 871-2708. Executive Vice President: Dr. Wayne Patterson—Contract Date: November 17, 1974—fully installed.

Methodist Hospital of Indiana, 1604 North Capital Avenue, Indianapolis, Ind. 46202, telephone (317) 924-6411. Vice President for Administration: Mr. Clyde Fields—Contract Date: August 12, 1976—85 percent installed.

National Institute of Health, Clinical Center, 900 Rockville Pike, Bethesda, Md. 20014, telepone (301) 656-4000. Deputy Director: Dr. Jay Shapiro—Contract Date: July 1, 1975—95 percent installed.

Nebraska Methodist Hospital, 8303 Dodge Street, Omaha, Nebr., telephone (402) 397-3000. Assistant Administrator: Mr. Clark Mathisen—Contract Date: June 1, 1973—fully installed.

St. Barnabas Medical Center, Old Short Hills Road, Livingston, N.J. 07039, telephone (201) 533-5000. Executive Director: Mr. John D. Phillips—Contract Date: June 12, 1974—fully installed.

University of Colorado Medical Center, 4200 East Ninth Street, Denver, Colo. 80220, telephone (303) 394-7448. Vice Chancellor for Health Affairs: Mario Pasquale—Contract Date: August 27, 1976—fully installed.

Medical College of Virginia, 1200 East Broad, Richmond, Va. 23298, telephone (804) 770-2468. Administrator: Dr. R. B. Young—Contract Date: September 15, 1977—50 percent installed.

NEW CONTRACTS

Jewish Hospital of St. Louis, 216 South Kingshighway, St. Louis, Mo. 63110, telephone (314) 454-7000. Executive Director: Mr. Irwin Albrecht—Contract Date: September 18, 1978—installation just begun.

Strong Memorial Hospital of University of Rochester, River Campus, Rochester, N.Y. 14627, telephone (716) 275-2121. Executive Director: Mr. Allan C. Anderson—Contract Date: September 22, 1978—installation just begun.

REPORT SUBMITTED BY MR. WHITEHEAD IN HIS LETTER OF OCTOBER 12, 1978

ANALYSIS OF ALTERNATIVE METHODS OF HOSPITAL LABORATORY OPERATIONS

Objectives

The objectives of this study are as follows:

(1) To identify the different methods of operations of laboratories providing hospital services.

(2) To establish costs including effect of variable factors.

(3) To report on the effect of the different methodologies of laboratory operations on the medical operations of the hospital.

(4) To make a comparative analysis of the various methods of making laboratory determinations for hospital patients.

(5) To identify trends in work loads and costs of hospital laboratories.

Methods

The methods used in this report included the analysis of studies of detailed operations of 66 hospitals of various sizes. These studies were made at various times over a seven year period. Adjustments were made for work load growth and inflation in developing comparative analysis

Sample

The hospitals used in this sample were classified into four meaningful groups as follows:

(1) Those hospitals that operate their own laboratory with at least 90 percent of the laboratory work performed in and on the premises; laboratory under the overall direction of a pathologist on salary.

(2) Those hospitals that operate their own laboratory with at least 90 percent of the laboratory work performed in and on—premises; laboratory under the direction of a pathologist compensated according to revenue received from the laboratory in whole or in part.

(3) Those hospitals that have an on-premises laboratory operated under contract by a commercial firm where at least 90 percent of the hospital laboratory work is performed on site.

(4) Those hospitals where work is done in off-site commercial laboratory, with only stat work performed at the hospital.

(5) Those hospitals here at least 60 percent of the volume of work is performed in a clinical laboratory in another hospital. The hospitals in this sample were further classified according to size of institution in number beds. Following is a breakdown by size according to the five groups listed above.

SIZE OF HOSPITALS IN SAMPLE ACCORDING TO GROUP CLASSIFICATION (I THROUGH J)

Group	Under 100 beds	100–199 beds	200–299 beds	300 Beds and over	Total
1	1	5	4	6	16
2	3	12	13	6	34
3	2	2	2	1	7
4	2	1	1		4
5	4	1			5
Total	12	21	20	13	66

Within the five classifications above there are a number of mutations or combinations on both the methods of operations and compensation of the pathologist. There are wide variations in identifying laboratory revenue and expenditure in hospitals reporting. Following are the most common variables.

1. Laboratory operations

(*a*) In only nine of the 66 hospitals in the sample, performed all laboratory work. Of the remaining 57, at least some specific, esoteric tests were sent elsewhere.

(*b*) In all but 12 of the hospitals in the sample, the blood gas work was performed by technicians in the inhalation therapy department.

2. Compensation of pathologist

(*a*) Pathologists receiving their compensation in whole or in part from the revenue of the laboratory may receive a percentage of net, the revenue of the department less the allowances of Blue Cross, Medicare, Medicaid and bad debts; or a percentage of gross revenue, the revenue without deduction of the allowances which is more than the true amount of monies earned by the department.

(*b*) In one instance, the pathologist operated the complete department as a private enterprise, leasing the area in which the laboratory is located from the hospital.

(*c*) In other instances, the compensation bases (percentage of gross or net revenue of the laboratory) was different for inpatients and outpatients.

3. Financial reporting

(*a*) Generally the revenue of the laboratory is reported without reference to the allowances and in the sample of 66 hospitals the actual monies received was 22.6 percent less than the revenue shown for the department.

(b) In some instances the salary and/or other earnings of the pathologist was charged to the expenses of the laboratory department in the annual financial statement. In other instances, the expenses of the pathologist were charged under separate items such as "Physician and Medical expenses".

(c) In some instances the cost of drawing of blood, and taking of other samples, and transplanting the samples to the laboratory or other locations was charged to nusing service, this was particularly true in those instances where specimens were sent to an outside laboratory.

(d) The costs for entering reports from the laboratory on the patient charts are charged in a number of different ways.

(i) These reports are entered by laboratory personnel; in a limited number of cases the costs involved were included in laboratory expenses.

(ir) Where reports are transported by the laboratory to the patient unit, the charges of such transportation were included as expenses of nursing service.

(iu) In some instances a messenger service was charged with the responsibility of transporting reports to the nursing units. In approximately half of these instances, the messenger service expenses was included in administration expenses. In approximately half the instances, the expenses of the messenger service were charged to "nursing service".

Hospital workloads

Since 1973 the hospital work loads in the laboratory have increased significantly. The number of procedures performed on outpatients including patients in the emergency room has increased most dramatically. For the sixty-six hospitals in the study sample the number of outpatient laboratory procedures increased 114.3 percent from 1973 through 1977. The following table indicated the average work loads per bed per year for the sixty six hospitals in the sample, for years 1973 and 1977.

AVERAGE WORK LOAD PER BED 1973 AND 1977 LABORATORIES

	1973	1977
Average number of lab procedures per bed:		
Inpatients	497	730
Outpatients	90	194
Total	587	924

Following is a breakdown of the number of procedures per admissions major classification, average for 1973 and 1977.

NUMBER OF PROCEDURES PER INPATIENT ADMISSIONS 1973 AND 1977 (AVERAGE)

Procedure	1973	1977	Percent change
Hemotology	2.2	3.9	+77
Chemistry	4.2	6.3	+50
Urinalysis	1.9	1.9	
Serology	1.4	2.1	+50
Bacteriology	1.3	1.2	−8
Other	1.4	2.1	+50
Total	[1]2.4	17.5	[1]+41

[1]The number of admissions from 1973 to 1977 in the 66 hospitals sample increased 4.2 percent.

Variation in workloads

There were substantial variations in the distribution of the work loads by type of laboratory as indicated in Exhibit 1. In this exhibit the laboratories are classified according to groups defined in the sample under "Method". The greatest variations are in "other" types of procedure which includes such expensive procedures as cardiac related tests including: Creative phosphokianase, lactic dehydrogenase (LDH): serum glutomic oxalic transaminase (SGOT), and hydroxy butyric dehydrogenase (HBD); Endrocrine tests, such as asdostrone; Pathology such as bone marrow and genetic tests.

Group 4 hospitals where the majority of laboratory work is performed in off-site commercial laboratories had 30 percent fewer procedures per admission than the average of all hospitals in the sample. For "other" procedures which include sophisticated and expensive tests group A has 61.9 percent less then the average of 66 hospitals.

COMPARATIVE ANALYSIS OF WORK LOADS IN PERCENT (66 HOSPITALS) BY TYPE OF LABORATORY OPERATION—1977 (EXHIBIT 1)

	Group 1	Group 2	Group 3	Group 4	Group 5	Average
Outpatients procedures for inpatient admissions	27.3	36.2	30.2	4.6	11.2	21.0
Hemotology	3.6	4.3	4.1	3.1	3.6	3.9
Chemistry	6.1	6.7	5.8	4.6	5.2	6.3
Urinalysis	2.1	2.0	2.0	1.5	2.1	1.9
Serology	2.4	2.6	1.9	1.3	1.9	2.1
Bacteriology	1.7	1.4	1.0	.9	1.3	1.2
Other	2.6	2.3	1.8	.8	2.4	2.1
Total inpatient procedures	18.5	19.3	16.6	12.2	16.5	17.5

ANALYSIS OF UNITS OF COSTS

As stated earlier, there are wide variations in the methods of financial reporting in hospitals. In order to develop comparative costs of laboratories it was necessary to deduct from the laboratory expenditures the pathologist's compensation because the inclusion of this item is not uniformly included in costs. Other deductions included costs of labortory work related to transfusions, since again this was an area of wide variations in costs. Where laboratories had a cost attribution to drawings if samples, delivering of samples, communicating of results and entering of results in patient records, these items were excluded in order to obtain a comparative analysis of costs. It is useful, however, to note the cost of these operations.

Drawing of blood

Of the sixty six hospitals included in the sample the drawing of blood for samples was performed by laboratory personnel in 58 of the hospitals. The direct personnel costs for this function ranged from 23 to 36 percent of the cost of operating the department with a median of 24.3 percent.

Gathering of samples

In fifty of the sixty six hospitals studied, the gathering of samples, exclusive of drawing blood was performed by laboratory personnel. The range of cost was for 4.3 percent to 7.2.

Communicating of results

In a number of hospitals, it was found that telephone "Stat" requests for results was time consuming and often interfered with routine operations. However, it was found impossible to place a cost factor on this item.

The orderly distribution of laboratory reports was an item charged to the laboratories in fifty-seven of the sixty-six hospitals. The range of costs was from 4.4 percent of total laboratory costs to 11.4 percent with an average of 5.8 percent.

Entering of results on patient records

In only nine of the sixty-six hospitals were laboratory personnel charged with the responsibilty of entering results on the patient charts. It was not possible to develop an accurate cost item for this activity since it was combined with distribution of reports and explains why there is such a wide range in the percentage of laboratory costs for this item.

Pathologist's remuneration

The pathologists' and other physicians' compensations were included in 59 of the 66 hospitals laboratory costs. The range was 11.6 to 33.8 percent of the laboratory costs with an average of 21.8 percent.

Units of cost by group or type of laboratory

After the variables listed above were deducted the units of cost were determined by group or type of laboratory and are as follows:

LABORATORY COST PER PROCEDURE BY TYPE OF LABORATORY OPERATIONS (1977)

Procedure	Group 1	Group 2	Group 3	Group 4	Group 5
Hemotology	$1.16	$1.19	$1.15	$1.07	$1.10
Chemistry	.80	.77	.84	.75	.75
Urinalysis	.80	.78	.72	.67	.69
Serology	.69	.71	.64	.63	.65
Bacteriology	1.41	1.36	1.39	1.61	1.33
Other	2.21	2.15	2.21	2.71	2.33

The off-premises commercial laboratory (Group 4) has the lowest per unit cost for hemotology, chemistry, unrinalysis and serology, but the highest cost for bacteriology and "Other" procedures. On balance, where the work is predominately performed in another hospital laboratory (Group 5) provides the best cost structure; lowest in two costly categories, bacteriology and "Other"; second lowest in these categories, hemotology, chemistry and urinalysis; and third lowest in serology.

MEDICAL STAFF REACTION

For eleven of the sixty-six hospitals in the sample, interviews were held with representatives of the medical staff of the hospitals involved. The division of hospitals involved in staff interviews were as follows: Three in Group 1; three in Group 2; one in Group 3; two in Group 4; and two in Group 5.

Following is a summary of the most comments in sequence of the number of times made.

1. It is very important to be able to discuss the laboratory findings with the pathologist, bio-chemist or hemotologist.
2. Being able to get competent "stat" reports by phone is often important.
3. Having the same personnel responsible for the taking, processing and reporting on laboratory work is important and avoids avoidance of responsibility.
4. Large centralized laboratories could affectively do the sophisticated and unusual procedure.
5. More effective means of getting the laboratory reports on the patients "charts" could help reduce the length of stay.

METHODS OF CHARGING

Of the sixty-six hospital samples, thirty-one included a tabulation of "costs" and "revenue" for the "ancillory" revenue producing departments, including laboratories.

Following is a summary of the ratio of revenue-to-costs of these departments for the thirty-one hospitals with data in their 1977 annual financial report:

Summary of ratio of revenue to costs, 31 hospitals, to $1 cost

Department:	
Operating room	$1.65
Delivery room	.60
Emergency room	.74
Laboratories	1.63
Radiology	1.78
Nuclear medicine	1.69
Pharmacy	2.11
Anesthesiology	1.56
Inhalation therapy	1.98
Physical therapy	1.51
Average	1.56

As mentioned earlier the "allowance" which are treated in the financial statements as a lump sum deducted provided on the average 21.6 percent less monies than shown on the financial statement as "revenue"

SUMMARY

1. A study of sixty-six hospitals indicated that the laboratories operated in five distinct ways with a number of mutations. The five methods include:

(*a*) Operation of a laboratory with the pathologist(s) paid a percentage of laboratory revenue or income

(*b*) Operation of a laboratory under the direction of a commercial firm.

(*c*) Operation of a laboratory with pathologist paid a percentage of laboratory revenue or income

(*d*) Majority of laboratory work is sent to a commercial laboratory.

(*e*) Majority of laboratory work is sent to another hospital.

2. There are many costs, that are charged to the hospital laboratory that are usually not included in costs reported when laboratory services are purchased from a private laboratory. These include:

(*a*) Cost of taking of blood and other invasive samples

(*b*) Collecting of samples

(*c*) Reporting and delivering results to nursing units.

(*d*) Pathologists compensation

(*e*) costs of operating blood bank and transfusion.

3. These medical staff members were interviewed, they generally emphasized the importance of being able to communicate with the pathologist, and/or other laboratory experts concerning findings.

4. When all costs not directly related to the laboratory processing are removed there are no great overall differences in the costs of the different methods of operation of the laboratory, including purchasing service from a commercial laboratory.

5. The ration of reported "revenue" to costs for laboratories is not significantly different from that of other ancillary "revenue producing" department of the hospital.

The reported "revenue" does not indicate the "allowances" which constitute deductions for differences between charges and payments for Blue Cross, Medicare and Medicaid; and revenue for "bad debts" allowances are shown in the hospitals annual financial statement as a lump sum deduction and for the sixty-six hospitals sample averaged 21.6 percent.

RECOMMENDATIONS

1. There appears to be excellent opportunities for effective centralization, particularly for sophisticated procedures in the large hospital laboratories. The American Heart Association reported that in 1975 there were 885 hospitals participating in shared laboratory services. (i) Nearly all of these utilized larger hospitals for unique and sophisticated examinations. The following suggestions are offered to encourage the proliferation of such programs.

(*a*) Special consideration be given by the H.S.A's and the State Agencies for centralized hospital laboratories.

(*b*) Consideration be given for bonus payments to hospitals participating in shared hospital laboratory service, particularly if cost savings can be achieved.

(*c*) Federal support be provided for effective central hospital pathologist communication and consultation with participating hospitals.

2. One of the major cost factors and time in patient treatment, which obviously adds to the length of a stay, is the lag in getting laboratory reports on the chart and to the physician. The following is suggested regarding this problem:

(*a*) Priority approval be given for installation of equipment that will accelerate reports to patient charts.

(*b*) Bonus payments to hospitals providing systems for acceleration of reports to physicians via patient charts.

(i) Comparative statistics on health facilities and Population. P. 57: A.H.A.

HEW Submission for the Record in Response to Mr. Beilenson's Request for a List or Description of the Authorities that Already do Exist With Respect To Translating Findings of a National Center for Health Care Technology into Effect

Under the Health Planning Act there are four major types of functions which are being used to control health technologies and can be used to translate specific recommendations of the National Center for Health Care Technology into effect. These functions include the National Guidelines, the control of new institutional health services, the review of existing health services and the control over the use of PHS and related funds for the delivery of health services. For each of these interrelated functions there are well-defined, positive actions required by local, State and federal authorities which are prescribed in the enabling legislation and regulations. Meaningful sanctions can be imposed by the federal and/or State governments in support of these functions.

The National Guidelines for Health Planning in Sec. 1501(b)(1) of the planning law state that the Secretary shall include standards respecting the appropriate supply, distribution and organization of health resources. Health resources encompass or significantly affect all types of health care technologies. Health Systems Plans must be consistent with these health resource standards and as a result the standards must also be included in the State Health Plans. Adjustments to the standards must be approved by the Statewide Health Coordinating Councils. The first set of National Guidelines issued as regulations on March 28, 1978, contained standards for general hospital beds, obstetrical services, neonatal special care units, pediatric inpatient services, open heart surgery, cardiac catheterization, radiation therapy, computed tomographic scanners and end-stage renal disease.

Control over the introduction of proposed new institutional health services including those contained in the National Guidelines represents the main machanism for regulating the amount and types of new health technologies in the health delivery system. New institutional health services include technologies which are new services in an institution and expensive technologies which exceed a federally set minimum dollar value or exceed a lower state-set amount. In the law, Sec. 1513(f) requires the local Health Systems Agencies to review and make recommendations to the appropriate State Health Planning and Development Agency respecting the need for these new institutional health services proposed to be offered or developed in its health service area. Section 1523 (a)(4)(A) specifies that the State Health Planning and Development Agency is to serve as the designated planning agency if the State participates in the review program under Sec. 1122 of the Social Security Act; Sec. 1523 (a)(4)(B) requires the same State agency to administer a State certificate of need program which is satisfactory to the Secretary. As further defined in regulation Sec. 1122 reviews cover new services and capital expenditures exceeding $100,000 and certificate of need covers all new services and at a minimum capital expenditure of over $150,000. While certificate of need prohibits the introduction of a disapproved service, Sec. 1122 can only limit reimbursement under the Social Security Act for depreciation of a disapproved expenditure which could still be developed and offered in the State.

The review of existing institutional health services, "appropriateness review," by local Health Systems Agencies is required in Sec. 1513(g) and by the State Health Planning and Development Agency in Sec. 1523(a)(6). Existing services may include those previously approved under Sec. 1122 and certificate of need, those disapproved under Sec. 1122 but still developed, and those which did not require certificate of need or 1122 approval either because there was no certificate of need or 1122 agreement in effect or existing certificate of need laws did not cover their develop-

ment. Although there are no required federal sanctions against existing services which are determined to be unnecessary, the findings under appropriateness review are an important base for determining the need for new services. There has, in addition, been considerable discussion about whether reimbursement should be provided by third party payors for existing services which have not been approved.

Finally, in Sec. 1513(e) the Health Systems Agencies are required to review and approve or disapprove proposed uses of funds provided under the Public Health Service Act, the Community Mental Health Centers Act and the Comprehensive Alcohol Abuse and Alcohol Prevention, Treatment, and Rehabilitation Act of 1972. Projects supported under these acts include those which are directly involved in the development and introduction of new medical technologies into the health care delivery system. Representatives from each of the PHS agencies which support these projects are on the advisory group for the new Center for Health Care Technology. With advice from the National Center for Health Care Technology the Health Systems Agencies can play a key role in the control and appropriate introduction of these federally sponsored new technologies into the health care delivery system.

At the present time, all of the regulations covering these major functions have been published in final form or as Notices of Proposed Rulemaking. The first set of National Guidelines were published in final form in March 1978; final certificate of need rules, in January and April 1977; final Sec. 1122 regulations in March 1974. Notices of Proposed Rulemaking for the review of existing services and projects supported under the Public Health Service and related acts were released for comment in May 1978. State Health Planning and Development Agencies have received full designation in 7 States which means in these 7 States that all the organizations and administrative structure required under the planning law are in place and their certificate of need programs are considered to be satisfactory to the Secretary. Most of the remaining States are expected to receive full designation by July 1979.

Meaningful measurements of the effectiveness of these processes for the control of new medical technologies is difficult. In the case of the computed tomographic scanners, for example, it has been questioned whether these types of controls have had significant effect on the more rational introduction of this new and expensive technology. In areas where certificate of need laws and Section 1122 agreements which covered computed tomographic scanners have been in place, their effect on the unnecessary proliferation of this new technology has been questioned. At the same time, the number of new scanners being purchased and installed in the United States has decreased significantly in relation to previous years and earlier market projections. It has been argued that as a result of more effective controls already in existence the number of computed tomographic scanners will be approximately one-half of the projected estimate.

At the present time, standards for computed tomographic scanners are included in the National Guidelines. After December 1978, all revisions of local and State plans will contain standards for scanners which are consistent with the national standards. By 1980, all States must have effective certificate of need laws which cover new, expensive technology such as computed tomographic scanners. With these types of existing authorities already provided for by law, deliberations and recommendations by a nationally recognized group such as proposed in the new Center for Health Care Technology would permit more effective nation-wide controls over the introduction of similar types of new medical technologies and provide better standards against which to measure their effectiveness.

Attached are program information statements prepared by BHP/DRA which cover the certificate of need program, Sec. 1122 reviews, appropriateness review and review and approval of certain proposed uses of federal funds.

Program Information Statement on State Certificate of Need Programs

The National Health Planning and Resources Development Act of 1974 (Public Law 93-641) amended the Public Health Service Act by consolidating previous Federal health planning efforts and authorizing the development of new health planning agencies at the State and substate levels (State Health Planning and Development Agencies and Health Systems Agencies). The health planning law did not merely give these planning agencies the responsibility to develop plans for health services and facilities; it also provided them with the tools with which these agencies could carry out their plans. One of these tools is the review of new institutional health services and facilities through State certificate of need programs.

STATE CERTIFICATE OF NEED PROGRAMS

Certificate of need programs typically are based on State statute. They represent an exercise by the State of its police powers by prohibiting the development of health facilities and services without a certification that the facility or service is needed. New York enacted certificate of need legislation which became effective in 1966, and since that time many States have followed its lead. Currently, more than thirty States have enacted certificate of need legislation, and the District of Columbia administers a similar program on the basis of administrative regulation.

The determinations of need required by these State programs resemble "certificates of public convenience and necessity" which have long been utilized in regulating public utilities. They are intended to control the costs of health care by preventing the overbuilding of health facilities and the duplication of health services, and by redirecting available health resources to the areas in which they are most needed. Although the particular provisions of these programs vary from State to State, most of them specifically discourage the construction of hospitals, nursing homes, and related health facilities that are not in accord with State and local health plans. These certificate of need controls often apply when a proposal by one of these facilities exceeds some capital expenditure threshold, changes the bed capacity, or changes the health services offered. Because State certificate of need programs rely on health planning agencies in determining the need for proposed new health services and facilities, these agencies have come to play a key role in restructuring the health care system.

SECTION 1122 PROGRAM

These State programs have not gone unnoticed by the Federal government. In 1972, the Congress passed legislation (Public Law 92-603) which added section 1122 to the Social Security Act. The section 1122 program provides for the regulation of capital expenditures made by or on behalf of health care facilities and health maintenance organizations through a review process similar to that required in State certificate of need programs. State participation in the section 1122 program is voluntary; currently, more than thirty States and territories have signed agreements with the Secretary of Health, Education, and Welfare to participate in the program. Under terms of this agreement with the Secretary, a State-level health planning agency consults with the appropriate substate health planning agency in conducting reviews of proposed capital expenditures. A failure to obtain approval for a capital expenditure can result in the Secretary withholding reimbursement under Titles V, XVIII, and XIX of the Social Security Act (the Maternal and Child Health, Medicare, and Medicaid programs) in amounts related to the expenditure (depreciation, interest, and, in the case of proprietary institutions, return on equity capital). Beyond this sanction, the section 1122 review requirement appears to have had an impact on the availability of capital because commercial lenders and government loan programs usually require section 1122 approval before agreeing to help finance a health facility construction project.

FEDERAL CERTIFICATE OF NEED REQUIREMENTS

The Public Health Service Act, at section 1523(a)(4)(B), requires each State to administer a certificate of need program which is "satisfactory to the Secretary" of Health, Education, and Welfare. In the words of the statute, this requirement is intended to ensure "that only those serivices, facilities, and organizations found to be needed shall be offered or developed in the State." The statute goes on to provide minimum procedures designed to ensure that applicants for certificates of need receive timely consideration of their proposals, to guarantee a fair and open review process, and to provide an appeals mechanism for those dissatisfied with the actions taken by health planning agencies. Further, the statute details minimum considerations to be used by health planning agencies as they develop specific criteria for the review of new institutional health services and facilities.

It has become common practice for States to recognize the public utility status of hospitals and related health facilities. By requiring each State to administer a certificate of need program "satisfactory to the Secretary," the Federal government does not call for any radical departure from the techniques currently being utilized by the States.

Rather, the Federal approach toward certificate of need has drawn upon the experience of the States and the Department of Health, Education, and Welfare in administering certificate of need and section 1122 programs, so that the weaknesses of these programs can be overcome.

The Bureau of Health Planning and Resources Development within the Department of Health, Education, and Welfare is charged with implementing the health

planning program. A major responsibility of the Bureau has been developing the Federal specifications for satisfactory certificate of need programs, and in the next few years considerable effort will be expended in assisting States to understand these specifications and to comply with them. It is anticipated that all States which currently administer certificate of need programs will be required to modify their programs to some degree in order to make them consistent with the Federal certificate of need regulations. Whether this wll involve State legislative activity, executive orders, rule-making, or combinations of each of these actvities will depend on State legal and political factors. In any case, it is clear that considerable effort will be necessary to develop satisfactory programs in those States that already administer certificate of need programs, as well as those that do not.

Much effort is underway at the State level to develop certificate of need programs that comply with the Federal requirements, and the first Federal evaluations of State programs are currently in progress. Because State health planning agencies may be designated by the Federal government on a conditional basis for no more than three years, and because a satisfactory certificate of need program is a prerequisite for full designation, legislative, executive, and administrative activity in the States in becoming increasingly urgent. The first State health planning agencies were conditionally designated on July 1, 1976; these agencies will have only until July 1, 1979, to meet all of the requirements for full designation, including the administration of satisfactory certificate of need programs. Further, the health planning law provides that if a State health planning agency for a State does not have a full designation agreement in effect by September 30, 1980, the Secretary of Health, Education, and Welfare "may not make any allotment, grant, loan, or loan guarantee, or enter into any contract," under the Public Health Service Acts for the development, expansion, or support of health resources in such States until such time as such an agreement is in effect.

SPECIFIC REQUIREMENTS

The requirements for satisfactory State certificate of need programs were published in regulations which appeared in the FEDERAL REGISTER on January 21, 1977, and were amended on April 8, 1977. They were developed after analyzing existing State certificate of need programs and after taking into account more than 3,000 public comments. The regulations do not address every aspect of a State's certificate of need program; they represent only minimum requirements and, as such, do not preclude States from administering more comprehensive or stringent programs.

In order to comply with the minimum Federal requirements, State certificate of need programs must:

1. Cover all non-Federal health care facilities (e.g., hospitals, nursing homes, and ambulatory surgical centers) and health maintenance organizations, regardless of ownership (see the Federal regulations at 42 CFR 123.401);

2. Require a certificate of need before a covered facility may: (*a*) Be constructed, developed, or otherwise established; (*b*) make a capital expenditure (with certain exceptions) in excess of $150,000; (c) substantially change its bed capacity; (*d*) offer a new health service; (*e*) make predevelopment expenditures in excess of $150.000; and (*f*) make any arrangement or commitments for financing. (See the Federal regulations at 42 CFR 123.404.)

3. Provide sanctions sufficient to ensure that health facilities and services found not to be needed are not offered or developed (see the Federal regulations at 42 CFR 123.405);

4. Develop and follow review procedures which, among other things, provide that: (*a*) substate health planning agencies participate in the certificate of need process; (*b*) the review process will be an open one and will protect the rights of the applicant, as well as the public. (See the Federal regulations at 42 CFR 123.406, 123.407 and 123.408.)

5. Develop and apply review criteria which take into account relevant State and local conditions and circumstances (see the Federal regulations at 42 CFR 123.406 and 123.409);

6. Provide that certain specific findings are made before a certificate of need may be granted for proposed inpatient facilities and health maintenance organizations (see the Federal regulatons at 42 CFR 123.410 and 123.411).

SECTION 1122 PROGRAM INFORMATION STATEMENT

Section 1122 of the Social Security Act was enacted as part of the Social Security Amendments of 1972. Its purpose is to reduce the incentives for health care facilities and health maintenance organizations to make capital investments in unneeded facilities and equipment and to ensure that Federal reimbursement under the

Medicare, Medicaid, and Maternal and Child Health Programs is not used to support unnecessary capital expenditures. The Department has established regulations to implement the statute and policy guides to deal with the more complex aspects of the program. States participate in the program on a voluntary basis: thirty-seven States currently have agreements with the Department to administer section 1122.

Coverage

Certain capital expenditures are subject to review if they are proposed by or on behalf of covered health care facilities or health maintenance organizations. Covered health care facilities are hospitals, nursing homes, ambulatory surgical facilities, and kidney disease treatment centers. Capital expenditures subject to review and defined as those which (i) exceed $100,000, or (ii) would result in a change in bed capacity, of (iii) would add or terminate a health service.

Review process

States are given the substantive role in this program. The State designated planning agency (DPA) receives an application for approval of a capital expenditure proposed by a health care facility or health maintenance organization (HMO) and decides whether the capital expenditure is subject to section 1122 review. A decision by the DPA that a capital expenditures is subject to review may be appealed to the Regional Health Adiministrator (RHA) in the appropriate Regional Office of the Department of Health, Education, and Welfare.

The DPA, after considering the findings and recommendation of the local health systems agency and the State Hill-Burton agency, if any, submits its findings to the RHA. The first finding is whether the health care facility or HMO gave notice of the intent to make the capital expenditure at least 60 days prior to the expected date of obligation ("timely notice"). The other finding made by the DPA is whether the proposed capital expenditure is in conformity with standards, criteria, and plans developed pursuant to the Public Health Service Act (or the Mental Retardation Facilities and Community Mental Health Centers Construction Act of 1963).

Fair hearing

When the DPA finds that a proposed capital expenditure is not in conformity with applicable standards, criteria, and plans, the DPA must offer the proponent the opportunity for a fair hearing. If a fair hearing is held, the hearing officer may make an independent judgement as to whether the proposed expenditure is in conformity with applicable standards, criteria, and plans. He may also consider whether the DPA conducted its review in accordance with the law and regulations. The adequacy or correctness of the plans, criteria, and standards themselves, however, is not subject to review in the fair hearing. The hearing officer's decision, if it reverses or revises the DPA's finding(s), supersedes the finding(s) of the DPA. This decision would be considered the final State finding unless any judicial review resulted in futher modification of these findings or the hearing officer remanded the case to the DPA for further action.

Determination by the RHA

The responsibility to determine whether reimbursement related to capital expenditure will be withheld from payments to a facility under titles V, XVIII, and XIX has been delegated to the RHAs. Upon receipt of the DPA's findings regarding a proposed capital expenditure, the RHA first determines whether the expenditure is subject to review. The RHA then makes a determination as to whether the DPA found that the expenditure would or would not be in conformity with applicable standards, criteria, and plans (as modified by any fair hearing or judicial review) and whether the proponent gave timely notice. The RHA is authorized to make an independent judgement on the latter issue, but is not so authorized with respect to the question of conformity. If the proposal is subject to review, if the DPA has made a finding of conformity, and if the RHA determines that timely notice was given, then a determination that reimbursement will not be withheld must be made. The statute authorizes the withholding of reimbursement in only two instances:

1. If the DPA found, after consulting with the areawide planning agency and affording the proponent an opportunity for a fair hearing, that the expenditure would not be in conformity with applicable standards, criteria, or plans, or
2. If the RHA determined that timely notice of the intent to make the capital expenditure was not provided.

Last, in certain unusual cases, the RHA may determine, after consulting with the designated national advisory council, that captital reimbursement will not be excluded from payments despite the presence of one or both of the bases for withholding listed above. This determination may be made if such exclusion would (1)

discourage the operation of an efficient health care facility which provided comprehensive health care services, (2) be inconsistent with the administration of titles V, XVIII, and XIX of the Act, or (3) otherwise be inconsistent with the effective organization and delivery of health servces.

Reconsideration

Any person dissatisfied with a determination by an RHA may request the Administrator of the Department's Health Resources Administration to reconsider it. To be effective, such a request must be received by the Department within six months of the date of the RHA's determination. The Administrator may reconsider those same issues considered by the RHA: whether the proponent gave timely notice, whether the DPA made a finding of confomity of lack therof, and, in the case of a finding of nonconformity, whether the DPA followed the required procedures. The Administrator, like the RHA, is not authorized to make an independent judgement as to the conformity of the proposed expenditure with standards, criteria, and plans.

Sanction

The RHA forwards copies of the determinations to the Regional representatives of the Medicare, Medicaid, and maternal and Child Health Programs. In determining payments to a health care facility of HMOS, these representatives will withhold amounts related to any capital expenditure for which the Regional Health Administrator has issued a determination to withhold. In addition, if a facility claims reimbursement for a capital expenditure which was not submitted for review, the fiscal agents or intermediaries will submit these cases to the RHA for a determination as to the withholding of reimbursement. The policy in the Federal Register on January 26, 1977, sets out the policy on the period of withholding to be applied when a facility fails to give timely notice of a capital expenditure.

Some Issues Pertaining to Appropriateness Review

INTRODUCTION

A Notice of Proposed Rulemaking (NPRM) governing appropriateness reviews was published in the Federal Register on May 16 and was followed by a 45 day public comment period which ended on June 30. The Bureau is presently analyzing comments received and developing recommendations to the Secretary which may change the NPRM substantially. The proposed rules were re-issued on August 1 for another 30 days for additional comments on the issues listed below and others.

There is a wide divergency of views of how this function should be implemented. We have identified at least eleven (11) major issue areas from the comments thus far received. They are:

1. Services to be covered.
2. Definitions.
3. Data.
4. HMOs.
5. Agency Workload.
6. Levels of Review:
   a. Institution-specific Reviews.
   b. Areawide Reviews.
7. A/R workplan,
8. Review criteria.
9. Findings/Recommendations.
10. Review procedures.
11. Coordination.

STATUTORY BASIS FOR APPROPRIATENESS REVIEW

Section 1513(g) of the Public Health Service Act requires each Health Systems Agency to review the appropriateness of all institutional health services offered in its health service area. Such reviews are to be performed every five years, except that the initial reviews for appropriateness must be completed within three years after the agency receives full designation. Following these reviews, the HSA must submit recommendation to the State Health Planning and Development Agency(s) in the State(s) in which it is located. Section 1523(a)(6) and 1523(b)(3) require the SHPDA to consider these recommendations in performing similar State-level appropriateness reviews. The State Agency must complete its first cycle of appropriateness reviews within five years of the agency's initial full designation, but in any case within one year after receipt of an HSA recommendation for a service.

DEFINITION OF APPROPRIATENESS

A service will be found "appropriate" if it meets the needs of the population of the health service area. Such needs are defined by the review criteria and plans of the health systems agency and State Agency. These criteria must be related to the

availability, accessibility, acceptability, cost, continuity and quality of the service subject to review.

SERVICES SUBJECT TO REVIEW

All "existing institutional health services" are subject to appropriateness review. This includes those services being offered in the health service area at the time of the review, those offered at any time in the twelve months prior to the review and those planned to be offered at any time in the twelve months following the review. (For definition of institutional health service see 42 CFR 122.301(e) and 123.401(e) Certificate of Need and Review of New Institutional Health Services Regulations, January 21, 1977.)

LEVELS OF REVIEW

Appropriateness reviews can take place on two levels: areawide and institution specific—

(1) Areawide reviews will result in findings regarding the appropriateness of a service in the aggregate as it is delivered by all the institutions in the area or State.

(2) Institution specific reviews will result in findings regarding the appropriateness of a service in a particular institution.

Health planning agencies will only be required to perform areawide reviews for appropriateness at this time. It is anticipated that they will phase in institution specific reviews as they gain more experience with these reviews and as their resources permit.

PROCEDURES FOR APPROPRIATENESS REVIEW

Planning agencies must meet the requirements of Section 1532(b) of the Act and applicable regulations with respect to the procedures they follow in performing appropriateness reviews. These procedures must be developed and adopted in an open manner and in consultation and coordination with the Statewide Health Coordinating Council and the other planning agencies in the State prior to the performance of the function.

CRITERIA FOR APPROPRIATENESS REVIEW

Planning agencies must meet the requirements of Section 1532(c) of the Act and applicable regulations with respect to the use of criteria in performing appropriateness reviews. In addition, criteria should relate to the availability, accessibility, acceptability, cost, continuity and quality of the services subject to review. With regard to the review of any particular service, all six of these characteristics need not be addressed.

HSA/SHPDA/SHCC COORDINATION IN APPROPRIATENESS REVIEW

Coordination between areawide and State-level planning agencies and bodies is required by the Act and existing regulations, and is crucial to effective performance of the appropriateness review function. Because of the large work load associated with the function, appropriateness reviews should be performed in an integrated, coordinated and consistent manner so that the work of the HSAs and State Agencies is complementary. Therefore, the proposed regulations require that the State Agency, after consultation with the HSAs in the State and the Statewide Health Coordinating Council, establish definitions of services to be reviewed, priorities among those services and schedules for reviews. Review procedures and criteria used by HSAs and SHPDAs need not be consistent, although consultation on these matters between the HSAs, State Agencies and SHCCs is required.

PREPARING TO PERFORM APPROPRIATENESS REVIEW

Health systems agencies

An HSA may not perform the appropriateness review function: (1) during its initial year of conditional designation; (2) before it has established an HSP and AIP; (3) before the Secretary has given written authorization for such performance; and (4) before issuance of final regulations governing the function. After full designation an HSA is not required to perform the function until six months after the date of the final regulations. Procedures and criteria developed for use in these reviews must be consistent with the requirements in Section 1532 of the Act until final regulations on appropriateness reviews are published, at which time these regulations will govern.

The HSA must also develop a work program which describes how the agency will perform the function. This plan should show at least, how the agency will develop

procedures and criteria, how it will work with the State Agency and SHCC, what procedures it will follow in transmitting its recommendations to the State Agency, and, a timetable for completing its first cycle of appropriateness reviews.

State agencies

State Agencies may not perform appropriateness reviews unless they have received written permission from the Secretary and not until final regulations on this function have been published. State Agencies must, however, complete their findings regarding the appropriateness of a service within one year following the date on which an HSA submits its recommendations to the State Agency. Procedures and criterial developed by the State Agency in preparation for performing these reviews must conform to the requirements of Section 1532 of the Act until more detailed procedures and criteria for appropriateness reviews are established by final regulation, at which time those regulations will govern.

The State Agency must also develop and submit to the Secretary, a work program which describes in detail, how it will perform this function. This plan must include at least a description of how procedures and criteria will be developed, how the agency will establish the definitions of services, priorities among services and the schedules for reviews, how the agency plans to require providers to submit the data needed for these reviews and how the agency will meet the time requirements for completing its first cycle of reviews.

Reviews of health maintenance organizations

Title XV of the Act requires that existing HMO services be subject to appropriateness reviews. To protect HMOs from possible discrimination, however, planning agencies must use a limited set of specific criteria in any institution-specific reviews conducted on HMO services. In addition, HSAs and State Agencies must make special review findings which stipulate under what conditions an HMO service may or may not be found inappropriate.

Review and Approval of Certain Proposed Uses of Federal Funds by Health Systems Agencies and Statewide Health Coordinating Councils

Public Law 93-641, the National Health Planning and Resources Development Act of 1974, amends the Public Health Service Act by adding Titles XV and XVI to the PHS Act. In enacting this law, the Congress hopes to improve the health of residents in health service areas by increasing the accessibility, acceptability and quality of health care, and contain the cost of health care by preventing unnecessary duplication of health resources and services. The Congress expects that these objectives will be promoted by careful review of proposed uses of Federal funds to ensure conformance with the needs in the local health service areas, as reflected in the health systems plans of the health systems agencies (HSAs), and statewide needs as determined by the Statewide Health Coordinating Councils (SHCCs).

Scope of health systems agency reviews

Section 1513(e) requires the HSA to review and approve or disapprove proposed uses in its health service area of funds authorized under four acts: the Public Health Service Act; the Community Mental Health Centers Act; sections 409 and 410 of the Drug Abuse Office and Treatment Act; and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970. These proposed uses may be in the form of grants, contracts, loans and loan guarantees, and are reviewable if they are for the development, expansion, or support of health resources. The HSA is also required to review and approve or disapprove proposed uses in its health service area of funds made available by the State from allotment grants under these Acts for the same purposes.

Scope of SHCC reviews

In a parallel manner, section 1524(c)(6) of the Public Health Service Act requires the Statewide Health Coordinating Council (SHCC) to review annually and approve or disapprove any State plan and application (and any revision of a State plan or application) submitted to the Department as a condition to the receipt of any funds under the allotments made to States under three Acts: the Public Health Service Act, the Community Mental Health Centers Act, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and the Rehabilitation Act of 1970.

Exceptions

Section 1513(e) provides for a general exception to review in the case of proposed uses of funds appropriated for grants or contracts under Title IV (National Research

Institutes), Title VII (Health Research and Teaching Facilities and Training of Professional Health Personnel), and Title VIII (Nurse Training) of the PHS Act. However, uses of funds authorized under these titles are reviewable if the grants or contracts support: (a) The development of health resources intended for use in the health service area; or (b) the delivery of health services.

HSAs may review and comment on, not review and approve or disapprove, proposed uses of funds authorized under the Acts enumerated above for projects located on a Federally recognized Indian reservation, or certain Indian-owned lands and land areas held in trust in Oklahoma, or in native villages in Alaska.

The HSA review activity

The HSA review and approval or disapproval function may not be undertaken until the HSA has: (a) Been conditionally designated for at least one year; (b) completed a Health Systems Plan and an Annual Implementation Plan; (c) received written approval by the Department. In any event, the HSA may not perform this review and approval or disapproval function until issuance of final regulations. However, the HSA may review and comment on certain proposed actions by the Department that had been previously authorized by references in statutes and regulations to the predecessor CHP 314(b) agencies, as well as for other programs upon request.

The HSA is allowed 60 days for its review from the date of written notification to affected persons of the beginning of a review. The Department has proposed that notification should be made within seven days of receipt of the application. In the event of a disapproval decision on the application, the applicant has 30 days to request the Department to make funds available notwithstanding the HSA disapproval. When the Department considers such a request, it is required to give the appropriate State Health Planning and Development Agency 30 days to consider the HSA decision and submit its comments. If the Department still wishes to fund the project, a detailed statement of reasons must be given to the applicant, the HSA and the State Health Planning and Development Agency concerned.

Review activity by the statewide health coordinating council

Section 1524(c)(6) requires the Statewide Health Coordinating Council (SHCC) to review annually and approve or disapprove any State plan and application (and any revision of a State plan or application) submitted to the Department as a condition to the receipt of any funds under allotments made to States. These are sometimes referred to as "formula grants." The grants covered are those authorized by the Public Health Service Act, the Community Mental Health Centers Act, and the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment, and Rehabilitation Act of 1970. The SHCC is allowed 60 days to make such reviews. In the event of a disapproval, the Governor, or another agency of the Sate, may request the Department to review the SHCC decision and may submit at that time a response to the SHCC's decision. The Department may make the Federal funds available notwithstanding the SHCC disapproval but a detailed explanation or reasons must also be given.

The Department has determined that the statute does not require regulations for the SHCC review function. Therefore, SHCCs may review and approve or disapprove State plans and applications for allotments when the Regional Office determines they are duly constituted. A SHCC is considered duly constituted when the Governor has appointed the SHCC members, and the Regional Health Administrator, acting for the Secretary, has determined that the SHCC is in compliance with the State Health Planning and Development Agency Regulations, dated March 10, 1978. The State Agency Regulations also require the State Health Planning and Development Agency to assist the Statewide Health Coordinating Council in the performance of its functions generally. This includes its review under section 1524(c)(6) of the Act. The Bureau expects to provide guidance for SHCCs in conducting reviews of State plans and applications in September 1978.

Publication of the second notice of proposed rulemaking

The Department is presently drafting a second Notice of Proposed Rulemaking (NPRM) for regulations dealing with the HSA reviews of certain proposed uses of Federal health funds. The first NPRM was published on May 9 with a public comment period of 45 days. The second NPRM will include: (1) the Health Planning Amendments of 1978; (2) the criteria for determining which research and training grants and contracts are subject to review (section 122.403(c) previously reserved); and, (3) proposed modifications which reflect comments received on the May 9 NPRM.

The Department expects to publish the second NPRM for HSA reviews of proposed uses of Federal funds in the Federal Register later this year. Publication will include an invitation to interested persons and organizations to submit comments on the proposed rules.

Notice of programs subject to review and approval

To facilitate implementation of regulations on review and approval or disapproval, the Department will publish a list of programs which will be subject to such reviews, as well as a list of those programs for which review and comment has been requested by agencies for programs not subject to P.L. 93-641, such as Maternal and Child Health Services, Crippled Children's Services, and others. The list was published in proposed form in the May 9 NPRM and will be published as a Notice with the final regulations.

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1. (Insert PHS material re health planning law authorities).

2. *Medicare.*—Section 1862(a)(1) of the Social Security Act specifically prohibits Medicare payment for items or services which are not "reasonable and necessary" to diagnosis or treatment, or to improved functioning of a malformed body member. This requirement has been interpreted as limiting payment to those items and services that have been proven safe and effective, or that have been accepted as such by the medical community, and that are medically necessary.

In this context, if there is question about payment for a particular item or service, HCFA usually obtains medical advice from the Public Health Service (which may consult with other HEW components and outside experts) and issues instructions as to whether and under what conditions Medicare payment will be made. As appropriate, these decisions are also sent to State Medicaid agencies for their information.

Section 1862(a)(1) also provides a basis for denying or limiting coverage of items or services that are substantially in excess of the cost of other therapeutically equivalent items or services available to the Medicare patient.

In addition, the law also provides that amounts paid to hospitals, physicins, and others who provide covered services be reasonable (for example, sec. 1861(v)(1)(A) and 1842 (b)(3)(B) of the Act).

This enables HCFA to impose limits on reimbursement for expensive technology, which has been done, for example, in placing national limits on reasonable charge reimbursement for CT scans.

3. *Medicare and Medicaid.*—Section 1122 of the Social Security Act provides authority to withhold or reduce reimbursement for capital expenditures made by hospitals and certain other facilities if that expenditure is not consistent with State or local health planning requirements. The limitation applies to depreciation, interest and other expenses related to the unapproved expenditure. These capital expenditures include those of over $100,000 for plant and equipment, those that change the bed capacity of a institution or those that substantially change the services provided by an institution.

SUPPLEMENTARY SUBMISSION BY MR. DERZON

HCFA Fiscal Year 1980-81 Strategy

This is HCFA's first opportunity to propose major legislation. These changes are necessary to implement the objectives of HCFA. Our proposals are consistent with ongoing efforts to improve Medicaid and coordinate Medicaid with welfare reform and with current Departmental efforts in the national health insurance (NHI) area. In fact, these proposals are essential to lay the foundation for implementation of national health insurance.

The thrust of HCFA is to make the Medicare, Medicaid and the quality assurance programs more uniform, equitable, and efficient. Our proposals: Consolidate and coordinate Medicaid and Medicare to the maximum extent feasible; improve management and administration of HCFA programs; remove eligibility gaps and increase access to care of program beneficiaries; increase efficiency in the health care delivery and financing system and contain the rapid increases in health care costs.

Difficult choices and trade-offs must be made. Many needy people are not eligible for services from our programs and those that are eligible do not always receive the services they need. Yet, to expand eligibility and benefits without containing the rapid inflation in the health sector substantially increases program costs at a time of fiscal constraint. In fact, largely as a result of inflationary pressures, between FY 1976 and FY 1978, without major expansions in benefits, Medicare and Medicaid expenditures increased from $26.2 billion to $36.5 billion, an increase of 39 percent. This $10.3 billion increase accounted for 14 percent of the increase in the total Federal budget even though Medicare and Medicaid amount to only 8 percent of that budget.

HCFA programs must help contain the rapid increases in health care costs and foster increased efficiency in the health care delivery and financing system. Although Medicare and Medicaid cover 20 percent of the U.S. population and account for 25 percent of all health care spending, the programs are insufficient in and of themselves to achieve major structural reforms in the health care financing and delivery system. In fact, piecemeal efforts by Federal and State governments to control these costs have often resulted in reduced access to care for our program beneficiaries.

Today, Medicare and Medicaid are not accomplishing what they were designed to do in 1965. Our priority is to redirect the Medicare and Medicaid programs toward their initial goals—to provide access to needed care for low income and elderly people. Our proposals encompass: Program eligibility and benefits; Reimbursement reform; Financing; Program management and administration; and Delivery system reform.

I. PROGRAM ELIGIBILITY AND BENEFITS

Categorical restrictions and variations in State eligibility criteria make 25–35 percent of the population with incomes below the poverty line, roughly 9 million people, ineligible for Medicaid. Social security restrictions make over one million elderly and disabled people ineligible for Medicare Part A. For beneficiaries of both programs, benefits provided are not comprehensive and, for Medicaid, vary widely among States. HCFA's strategy is to eliminate major existing eligibility and benefit gaps in the Medicaid and Medicare programs and to gradually consolidate the Medicaid and Medicare benefit packages for acute care services.

Eligibility changes

The most egregious gaps in coverage occur in the Medicaid program where in some States more than 70 percent of the poor are not covered. Since Medicare gaps are not of the same magnitude (95 percent of the elderly have Medicare coverage), our eligibility proposals focus on closing the gaps in Medicaid and removing eligibility variations among States. Many of these proposals are already under consideration as options to coordinate Medicaid eligibility with welfare reform.

These proposals do not attempt to merge eligibility for Medicare and Medicaid. Form an eligibility perspective, Medicare and Medicaid serve two very different populations with the exception of a 4 million overlap out of a total of 48 million beneficiaries. However, by reducing State flexibility in Medicaid eligibility, our proposals move Medicaid toward the concept of uniform national standards for eligibility used by Medicare.

Require States to provide all SSI recipients with medicaid coverage (fiscal year 1980 Federal and State cost equals $400-500 million).—Medicaid eligibility standards should be the same as cash standards for SSI beneficiaries. Currently, States can limit Medicaid coverage for SSI beneficiaries by using State income standards instead of SSI standards. Repeal of this option would add 300,000 people to Medicaid in the 16 States that apply more restrictive standards. Coverage of "grandfathered" SSI cases should also be phased out.

Expand medicaid coverage to all families with incomes below State standards (fiscal year 1980 Federal and State cost equals $800 million–$1 billion).—Medicaid eligibility should be expanded to cover adults in both single and two parent families with incomes below State income eligibility lines. Current Medicaid eligibility policies exclude most two parent families from Medicaid, exacerbate the adverse family incentives of the welfare system, and result in inequitable and inconsistent eligibility standards across States. The Administration's CHAP proposal extends Medicaid to all low income children (FY 1980 Federal cost $519 million and State savings $10 million); this proposal covers the parents of these children and would extend eligibility to about 800,000 adults. As part of the welfare reform and NHI planning, HCFA is also considering adoption of uniform Federal income eligibility standards and extension of coverage to childless adults.

Improve operation of medicaid spend-down and mandate it in all States (fiscal year 1980 Federal and State cost equals $2–$4 billion).—A simplified spend-down provision should be mandated in all States. The Medicaid spend-down provision allows categorically eligible individuals whose incomes exceed State eligibility standards to be eligible for Medicaid if they have medical expenses which reduce their net income to below State standards. As such, it provides needed catastrophic coverage and removes the inequities and work disincentives caused by arbitrary eligibility cut-offs. Currently, 20 States do not have spend-down provisions.

Allow medicaid coverage of working disabled (fiscal year 1980 Federal and State cost equals $200–400 million).—The definition of disability for establishing Medicaid (not for cash benefits) eligibility should be liberalized. Under current Medicaid categorical eligibility requirements anyone who works is by definition not disabled and cannot be eligible for Medicaid. Our proposal removes the existing work disincentives for the many permanently disabled individuals who require health-related assistance in order to work.

Examine the feasibility of including currently ineligible groups under medicare.—HCFA is examining extending Medicare coverage to certain needy groups (e.g., widows and spouses of beneficiaries, disabled persons during 24 month waiting period, aged with insufficient social security coverage, and overseas beneficiaries) who are ineligible due to arbitrary waiting periods, demographic restrictions, and age difference in eligibility between cash and Medicare benefits.

Benefit package changes

The proposed benefit package changes are designed to improve and conform the acute care benefits among State Medicaid programs, and between Medicare and Medicaid. (Non-acute long term care services are considered in Section V.) The acute care benefits[1] in the Medicaid required services and the Medicare Part A and B benefit packages are essentially the same except for: family planning and EPSDT benefits in Medicaid; State imposed limitations on amount, duration, and scope of services under Medicaid; uniform limits on hospital and skilled nursing facility days and home health visits under Medicare; and cost-sharing under Medicare. State flexibility in setting Medicaid limitations on the amount, duration and scope of services and in selecting coverage of optional services leads to gross inequities among State Medicaid programs as well as lack of uniformity of acute care benefits between Medicare and Medicaid.

Establish uniform minimum standards for State Medicaid benefit packages (fiscal 1980 Federal and State cost equals $200–400 million).—States should be prevented from unduly restricting Medicaid benefits. Many States restrict benefits by imposing limits on the amount of services covered by Medicaid. For example, some States restrict the number of physician visits to one or two visits per month and one State limits such visits to 10 per year. HEW currently has the authority to require Medicaid services to be sufficient in amount, duration, and scope to reasonable achieve their purpose. These regulations should be revised to specify minimum standards for benefits. If necessary, additional legislative authority will be sought.

[1] Inpatient and outpatient hospital services, physician services, radiology and laboratory, home health, skilled nursing facility services and rural health clinic services.

Make prescription drugs a required benefit for both medicaid and medicare (fiscal year 1980 Federal and State cost for medicaid equals $2–3 million and for medicare $2–4 billion).—Outpatient prescription drug coverage is the major acute care benefit gap in Medicare and Medicaid and should be a required benefit under both programs. Drug coverage would benefit over 20 million Medicare beneficiaries and 26,000 Medicaid beneficiaries in Wyoming and Alaska, the two States that do not offer drugs as an optional Medicaid benefit. Generic dispensing for all drugs provided to Medicare and Medicaid beneficiaries would be mandated.

Establish a uniform national acute care benefit package for medicare and medicaid.—The Medicare and Medicaid acute care benefit packages would be conformed by merging Medicare Parts A and B, developing one uniform cost-sharing structure for Medicare, covering certain preventive services such as immunizations under Medicare and Medicaid, and standardizing and/or eliminating various Medicare and Medicaid acute care benefit limitations. We will evaluate the need to cover other benefits. These changes will provide the basis for consolidating the reimbursement, financing, and administration of the two programs (see below). For example, one fiscal agent could handle all the administrative and reimbursement functions (with the exception of eligibility determinations) for both Medicare and Medicaid.

II. REIMBURSEMENT REFORMS

The adoption of cost-effective and efficiency-inducing reimbursement methods by public and private payors is a critical first step in containing inflationary health care costs and laying the basis for reimbursement under national health insurance. The Administration's hospital cost containment proposal and ongoing efforts to develop a permanent hospital reimbursement system provide the basis for effective hospital payment. Thus, our initiatives concentrate on physician reimbursement reforms.

Medicare and Medicaid alone are not good instruments for controlling rising physician fees since they account for only 20 percent of all physician expenditures. Medicare and Medicaid physician fee limitations have resulted in physicians refusing to see Medicaid patients and increased out-of-pocket costs for Medicare beneficiaries when physicians "extra-bill" patients for amounts above what Medicare will pay. Moreover, the uniform customary, prevailing, and reasonable (CPR) charge reimbursement method employed by the Medicare program is difficult for beneficiaries and physicians to understand, is highly inflationary, and has resulted in large specialty and geographic fee differences. Under Medicaid, State determination of reimbursement methods and rates has resulted in low payment rates which often results in patients receiving care in more expensive hospital emergency rooms and outpatient departments.

The HCFA proposals would institute a more rational physician reimbursement system for Medicare, lay the basis for coordination among HCFA programs and private payors, and provide incentives for physicians to participate in HCFA programs.

Institute statewide fee schedules for both medicare and medicaid (fiscal year 1980 medicaid Federal and State cost equal $250–$300 million).—Fee schedules would be established in each State based on negotiations between physicians and HEW. Medicare payments in each State would be set at the fee schedule rates and Medicaid payments would be phased up to these rates. In 1980, Medicaid payments rates for ambulatory services would be required to be at least 80 percent of the fee schedule. In future years, all Medicaid physician services (both ambulatory and institutional) would be based on the fee schedule, thus conforming Medicare and medicaid physician payment rates.

Establish a joint medicare-medicaid physician participation policy.—This proposal institutes a uniform concept of physician participation for Medicare and Medicaid, uses incentives to encourage physicians to participate, and eliminates the current bill-by-bill assignment approach under Medicare which is confusing to beneficiaries and, in the case of unassigned claims, results in Medicare beneficiaries paying an unknown level of cost-sharing.

Physicians who agree to participate in both Medicare and Medicaid would be classified as particpating physicians. Various incentives (in addition to the higher Medicaid physician payment rates discussed above) such as payment of 100 percent of the fee schedule inclusive of cost-sharing and bonus payments would be employed to encourage physician participation. Directories of participating physicians would be made available to program beneficiaries.

For non-participating physicians two payment alternatives are under consideration. Under the first approach no Medicare and Medicaid payments would be made

for services provided by non-participating physicians. The less stringent second alternative would apply only to Medicare and would prohibit any direct Medicare program payments to non-participating physicians (e.g., the beneficiary would be paid and the physician would have to collect the entire bill from all Medicare patients).

III. FINANCING

Medicaid financing is based on open-ended Federal matching grants which result in 57 percent of Medicaid expenses being financed through Federal general revenues and the other 43 percent being financed through State and local revenues. On the other hand, Medicare Part A is financed through payroll taxes on currently employed workers while Part B is financed through premiums paid by the elderly (30 percent of Part B expenditures) and Federal general revenue contributions.

The current inflationary increases in Medicare and Medicaid outlays severely strain these financing sources, exacerbate the Federal Budget deficit, and threaten the financial viability of the Medicare Trust Funds. Furthermore, State Medicaid shares which are based on matching formulas of questionable validity, are predominantly financed from regressive general sales, excise, and local property taxes, while 70 percent of Medicare financing is based on regressive payroll taxes and premiums. In other words, the burden of rising Medicaid and Medicare expenditures is increasingly being borne by lower and middle income individuals. Furthermore, with the changing age structure of the U.S. population resulting in fewer workers supporting more elderly, the Medicare Part A Trust Fund under existing payroll tax rates will be bankrupt by 1988.

Revise current Federal-State financing of medicaid.—States are seeking fiscal relief and will be reluctant to support any expansion of Medicaid without increased Federal assistance. The extent of increased Federal assistance is dependent on the extensiveness of the proposed changes in Medicaid and the desirability of reducing or maintaining State levels of effort. The appropriate Federal share and matching rates for medical services and administrative expenditures are currently being evaluated. Increased Federal financing of Medicaid would permit implementation of new initiatives without substantially increasing States' fiscal burdens, provide more equitable and stable financing, and enable benefits, eligibility and reimbursement to be more uniform.

Study moving to more general revenue financing of medicare.—HCFA will study alternative methods for financing Medicare. A broad range of options, including general revenues, earmarked taxes, and special tax levies will be evaluated on the basis of tax incidence and revenue potential. Proposals resulting in a more progressive tax burden will be developed if warranted.

IV. PROGRAM ADMINISTRATION AND MANAGEMENT

Joint program development activities

The development of common and, where feasible, integrated administrative practices and functions is a primary objective of HCFA and will improve the efficiency of our program management. Joint program efforts for Medicare and Medicaid will be concentrated in the areas of uniform data collection, consolidated administrative functions, and fraud and abuse detection and control.

Collect uniform information to be used by both medicare and medicaid.—We are developing common statistical reporting requirements for Medicare and Medicaid with respect to providers' workload, administrative costs, and discharge statistics; standardized procedural and diagnostic coding systems; and common provider/supplier identification numbers. Furthermore, we are examining the potential for establishing comprehensive medical care provider profiles by merging Medicare Part A, Medicare Part B, Medicaid, and PSRO data.

Consolidate those administrative functions which are performed for both medicare and medicaid to the greatest extent possible (fiscal year 1980 Federal and State savings equals $10–$20 million).—We are assessing ways of integrating the administrative operations of Medicare and Medicaid to the maximum economic and practical extent. Consolidation of Medicare and Medicaid benefits and reimbursement clearly increases the potential for administrative coordination. Our activities include: improving operation and coordination of eligibility processes for joint Medicare/Medicaid beneficiaries, common inspection and evaluation of fiscal agents, processing of claims for beneficiaries of both programs by one fiscal agent, development of a common "best practice" approach to contracting for claims processing

management services, joint Medicare Part A and B and Medicare/Medicaid claims processing, and joint hospital audits, cost reviews, and settlements for providers participating in both programs. Finally, we are developing a uniform approach to certifying and monitoring providers participating in HCFA programs.

Improve fraud and abuse detection and control (fiscal year 1980 Federal and State savings equals $35–$100 million).—HCFA is increasing its capacity for preventing and detecting program fraud and abuses. We plan to provide for claims data sharing between Medicare and Medicaid to improve our ability to detect fraud, abuse, and/or incorrect payments between the programs. We are working with Medicare contractors and State Medicaid agencies to increase their fraud and abuse detection and control capabilities, including development of minimum standards, assessment of their performance, and improved reporting of fraud and abuse activity. We are working closely with the Inspector General and the Justice Department on Project Integrity and in the conduct of criminal investigations. Furthermore, we have been publicizing our concerns with program fraud and abuse and the results of our control efforts.

PSRO's

PSROs are an important part of our strategy to assess quality and use of services. Although the exact structures of an ideal program may be open to debate, some forms of physician organizations are necessary to control the use of services. There are several major elements of our strategy over the next two or three years.

Achieve nationwide coverage for hospital review in 1979.—All PSROs will be performing hospital reviews in fiscal year 1979. We will designate alternative organizations, such as States, fiscal agents, and out-of-area PSROs to perform these reviews in areas without PSROs. Beginning this summer, nonperforming PSROs will be defunded and replaced by alternative review organizations. The selection of alternative review organizations will be designed to maximize our knowledge of which types of organizations are most effective.

Designate PSROs by type of review performed.—We are studying the desirability of permitting PSROs to be fully designated by type of review performed. This would allow them to be fully designated for hospital review only and reduce the pressure to fund long term care (LTC) review. (Currently, PSROs can remain conditional for a maximum of four years and must perform LTC review to be fully designated.) LTC review would be undertaken only in those areas that show high promise and clearly articulated State support or where the State has failed to perform reviews adequately, but the PSRO has demonstrated high standards of performance. A high degree of selectivity will be exercised with regard to new starts, and LTC review at nonperforming PSROs will be terminated. We are also considering a legislative amendment to remove the requirement that ambulatory care review by undertaken two years after the PSRO is fully designated.

Experimentation and program evaluation.—Experimentation and scientifically valid evaluations are receiving high priority. A major round of evaluation was completed last summer. While we are continuing our efforts to evaluate PSROs, no new results will be available before the summer of 1979.

V. DELIVERY SYSTEM REFORMS

HCFA programs have a major impact on and are strongly affected by the health care delivery and financing system. Thus, improvements in HCFA programs should be coordinated with efforts undertaken by other Departmental components, other Government agencies, and the private sector. Our specific concerns are in the areas of long term care, physician supply and general delivery system reform.

Long-term care reform

In fiscal year 1980, HCFA program spending for long term care services will amount to roughly $9 billion. Thirty-eight percent of Medicaid expenditures, about $8 billion in 1980, will go for long term care services. The major rationale for long term care reform is to: lessen the biases of Medicaid reimbursement toward costly institutional care; expand the availability and use of in-home and other community-based services; and improve coordination among various funding programs and services.

As you know, we are preparing a paper on long term care policy strategies to seek your guidance on whether to launch a major reform initiative in fiscal year 1980. Several types of options are being considered:

Retain the existing structures of such programs as Medicare, Medicaid, Social Services, and Older Americans while modifying certain elements to improve coordination, uniformity, and public understanding;

Create a new long term care program; nursing home and in-home benefits from Medicaid, Social Services, and Aging program would be removed from these programs and consolidated in the new program;

Replace Medicaid long term care services with a formula grant to the States;

Establish a fixed-budget (closed-ended) grant to communities for long term care along with increased flexibility in provision and organization of services;

Expand Medicare to create a comprehensive health program for all aged, and modify its financing to include trust funds, general revenue, and sliding-scale payments by users.

Until these possibilities have been more fully and carefully analyzed we are planning to undertake major demonstrations to test the feasibility and replicability of alternative financing and delivery modes and recommend short-range, relatively minor changes in benefits. For example, Medicare home benefits should be modified to remove the three-day prior hospitalization requirement and to add homemaker services.

Supply of physicians

We believe that the current overall supply of physicians is adequate, although distribution problems remain. Yet the current training pipeline will increase the number of physicians per capita by 35 percent by 1990. Given physicians' ability to generate demand for their own as well as other health services, we are deeply concerned about the impact of this increase in physician supply on HCFA and total health spending.

We support initiatives to:

Improve loan programs to allow medical students to pay a greater portion of their educational costs;

Liberalize third party reimbursements to primary care residency programs;

Review financing and reimbursement policies relating to undergraduate and graduate medical education.

General delivery system reforms

HCFA programs significantly affect the delivery system in a variety of ways. These include establishing quality standards for medical care providers, establishing precedents with respect to new reimbursement techniques, and influencing the development of innovative service delivery systems. Our proposed initiatives will result in making private markets work better. Some of our initiatives apply to Medicare and Medicaid alone while others apply across the board to the entire system. Our Medicare and Medicaid initiatives include:

Re-examining our provider certification and standards criteria for institutional and ambulatory settings to assure quality and cost effectiveness;

Evaluating Medicare reasonable cost reimbursement of skilled nursing facilities and home health agencies;

Using a "prudent buyer" approach for purchasing hospital, skilled nursing facility, durable medical equipment, and laboratory services under Medicare and Medicaid and examining the consequent issues of narrowing of freedom of choice.

Our systemwide initiatives include:

Requiring that insurance companies disclose, in understandable form, the inclusion or exclusion of specific benefits and the benefit-payout ration, i.e., the ratio of benefits paid to premiums. This measure would increase price competition for private insurance, especially for individual policies;

Working with the Labor Department to examine the need for Federal regulation of private insurance resulting from recent pension reforms (ERISA) and subequent judicial decisions which exempt self-insurance pools from State insurance laws;

Encouraging the use of alternative non-regulatory delivery and reimbursement mechanisms such as HMOs, Health Care Alliances, and other non-traditional mechanisms which encourage competition;

Requiring doctors, pharmacists, optometrists, and other suppliers to make available information on prices, hours of access, and extent of certification or accreditation;

Supporting FTC efforts to prohibit State anti-substitution laws which preclude pharmacists from using lower priced generic drug equivalents.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

Honorable James H. Scheuer
Chairman, Subcommittee on Domestic and International
Scientific Planning, Analysis and Cooperation
Committee on Science and Technology
House of Representatives
Washington D.C. 20515

Dear Mr. Scheuer:

In his testimony before your Subcommittee on October 6, 1978, Mark Novitch, Associate Commissioner for Medical Affairs, Food and Drug Administration stated that he would send, at a later date, a summary on CT scanners. This was stated on page 50 line 916 of the hearing transcript.

I have enclosed that information, which should complete our submissions for that hearing.

If you have any questions concerning these materials, please call me or Charles R. Banks of my staff at 443-3793.

Sincerely yours,

Robert C. Wetherell Jr

Robert C. Wetherell, Jr.
Associate Commissioner
for Legislative Affairs

Enclosure
Summary CT scanners

FOOD AND DRUG ADMINISTRATION

Additional

Submission for the Record

Hearing Before the

Subcommittee on Domestic and International
Scientific Planning, Analysis, and Cooperation

Committee on Science and Technology

House of Representatives

October 6, 1978

36-163 O 79 - 21

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION
ROCKVILLE, MARYLAND 20857

November 16, 1978

COMPUTERIZED AXIAL TOMOGRAPHY (CT SCANNERS)
Summary of Activities

Regulatory and Compliance

The Bureau of Radiological Health (BRH), under the regulatory authority of P.L. 90-602 has developed a Federal Performance Standard for Diagnostic X-ray Systems, 21 CFR 1020.30. Computerized Axial Tomographic scanners (CT scanners) are subject to the same requirements under this standard as are other general purpose diagnostic x-ray systems.

Due to several compliance activities relating to CT systems and after two open meetings with manufacturers, an evaluation of the Diagnostic X-ray Standard was made to determine how well it applies to CT x-ray systems. This evaluation has led to the conclusion that amendments to the x-ray standard are necessary to provide for adequate radiation safety of such systems. A notice of intent on this subject was published in the FEDERAL REGISTER of September 30, 1976 (41 FR 43180). A copy is attached.

A draft amendment to the standard concerning CT x-ray systems was mailed to manufacturers and interested parties for review on March 24, 1978. As a result of comments received from the TEPRSSC members and the public, BRH has mailed a second draft amendment to the public for review (October 27, 1978). A notice of proposed rulemaking (NPR) is scheduled to be published in the FEDERAL REGISTER during the summer of 1979.

Technical Analysis and Methodology

Our principal efforts on CT equipment have been directed toward the development of amendments to the Federal Performance Standard to make it more relevant to the special nature of this class of product. The regulation of CT performance presents a complex and interesting problem in that the devices themselves are mechanically and electronically much more complex than conventional diagnostic x-ray equipment, yet the images produced are simpler and more susceptible to quantitative analysis than conventional radiographs. Of special interest is the fact that the coupling between radiation dose and diagnostic information is tighter, more evident, and itself more accessible to study in the case of CT than in any other diagnostic radiological procedure. The impact of imaging performance on utilization is yet to be addressed but is accessible and we have collected, though not analyzed, some data bearing on this matter.

In light of the above, our efforts have had two main thrusts: studies of radiation dose and studies of imaging performance.

In the area of radiation dosimetry we have designed dosimetry systems and conducted field studies. In our first experimental studies of EMI equipment, we learned that the geometrical distribution of radiation dose is confined to a region in space which is small but in some cases considerably larger than the anatomical region studied. Large changes in dose occur over small distances. We quickly became convinced that either a spatially continuous dosimetry medium such as film or a large number of small dosimeters such as lithium fluoride thermoluminescent dosimeter (TLD) in a close geometrical array was necessary. We have developed plastic phantoms for such measurements and use up to 500 TLD's to map the dose distribution from a single scan.

We have used the dosimetry systems which we have developed to study CT machines in this locality and in the eastern U.S. This past summer, in collaboration with two medical physicists from Memorial Sloan-Kettering Cancer Center in New York, and one each from Middlesex and St. Bartholomew's Hospitals, London, we conducted a field survey of 21 CT machines in the eastern U.S. representing ten manufacturers and each of the four extant generations. Data on imaging performance, radiation dose, and utilization were collected. The radiation dose data are presently being analyzed and assimilated. This is probably the most comprehensive and detailed study of CT equipment yet undertaken. This study is being continued in the UK and on the European continent by the British investigators with our dosimetric support. We anticipate having a large amount of data on within-model variation of both radiation dose and imaging performance.

In the analysis of imaging performance, we have been applying to CT a formalism we had previously developed for assessing the imaging performance of conventional radiographic systems. The extension of this formalism with concepts taken from information theory seems very successful to date and we are enthusiastic about the results. We believe that we have developed a fundamental measure of the imaging performance of a CT device. A further extension of this formalism has had some limited success in predicting the performance of observers viewing CT images. We are now designing both theory and experiments to relate this measure to radiation dose.

As this work progresses, we will begin the development of regulatory performance standards for CT products based on this formalism. This may have some impact on equipment availability by reducing the number of models on the market. It is likely to effect an improvement in the imaging performance of most CT products. The implications of this for diagnostic performance and utilization are yet to be seen.

Quality Assurance and Utilization

Concurrently with technical analysis and methodological development, the Bureau is planning a three-pronged survey to evaluate potential sources of unnecessary radiation exposure from CT scanners due to:

- Poorly designed or poorly functioning equipment, causing wasted dose and/or poor image quality.
- Poor user technique or suboptimal performance correctable via education and quality assurance (QA) programs.
- Inappropriate or excessive use of the modality.

The survey will be performed in a statistically selected sample of about 40 facilities representing a range of facility types, sizes, locations, and equipment type. The survey is designed to collect from each facility, data in three areas of interest and concern:

- An imaging/dosimetry survey will assess the performance of each CT unit and measure representative doses delivered.
- A questionnaire will be completed by each technologist operator to determine current user training and QA practices, to evaluate what additional educational/QA resources may be needed.
- Information will be collected on 250-500 procedures to include patient characteristics, indications for examination, type of referring physician, scan results, and impact of the procedure on diagnosis and/or patient management.

Results of this survey will be used: 1) to develop survey and analysis techniques enabling FDA and State radiation control personnel to evaluate CT performance; 2) to properly develop QA programs and training materials for CT; and 3) to address any inappropriate use of CT suggested by the survey through development of high-yield criteria.

A pilot test of survey procedures has recently been completed at 7 CT facilities and that data is currently being analyzed and evaluated. Preliminary results should be available in one to two months.

Training and Education

A series of videotape training materials has been developed for users of CT equipment and is being distributed. These address the principles of CT imaging, quality assurance for CT and the medical applications of CT. These will be modified or supplemented as indicated by the results of the above survey.

Consumer information requirements for CT are essentially the same as for other diagnostic x-ray procedures, and the current consumer education and information programs are believed to adequately address them. As special needs become apparent, appropriate modifications or additions to that program will be made.

Attachment

federal register

THURSDAY, SEPTEMBER 30, 1976

Vol.41—No.191
9-30-76

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Public Health Service

Food and Drug Administration

RADIOLOGICAL HEALTH

HIGHLIGHTS OF THIS ISSUE

X-RAY EQUIPMENT
HEW/FDA issues advance notice of proposed rule making amending performance standard to include tomographic X-ray systems; comments by 12-29-76 43180

that are not addressed in the present standard.

Under authority of the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.), FDA administers an electronic product radiation control program to protect the public health and safety. This authority provides for the development and administration of radiation safety performance standards for electronic products. A radiation safety performance standard for diagnostic x-ray systems and their major components was established on August 15, 1972 (37 FR 16461), and became effective on August 1, 1974 (The extension of effective date was published in the FEDERAL REGISTER of June 12, 1973 (38 FR 15644)).

The amendments under consideration would change the requirements of § 1020.31(a)(2) as they apply to x-ray systems used for pantomography or to tomographic systems that use reconstruction techniques to obtain an image. As used here, pantomography is an examination process that produces a radiographic panorama of a curved layer of tissue using an x-ray system in which the x-ray source and film holder rotate about the object being imaged on one or more axes, e.g., the dental panoramic x-ray system that produces an image of the entire dental arch on a single radiograph. Tomographic systems that use reconstruction techniques to obtain an image are systems that do not use x-ray film or its equivalent to obtain an image directly, but employ analog or digital means to construct the image, e.g., systems employing the technique known as computerized tomography.

The requirement in § 1020.31(a)(2) for automatic resetting of the timer to its initial setting or zero upon termination of exposure is not appropriate for both types of tomographic systems. Such tomographic systems are capable of providing useful diagnostic information from interrupted exposures that are resumed and completed. The amendments under consideration would permit means to be provided for these tomographic systems to resume and complete such interrupted exposures.

The Commissioner of Food and Drugs is also considering amendments to § 1020.31(f) that would more clearly define the x-ray field limitation and alignment requirements for tomographic systems. Clarification of these requirements has been stated in letters to manufacturers from the Bureau of Radiological Health as an interim measure, and amendments may be needed to reflect these interpretations in the regulations. Other amendments may also be needed to assure protection of the public health and safety during use of these systems.

The Commissioner invites comments and suggestions on these contemplated proposals as well as information and data concerning other aspects of the performance of tomographic x-ray systems for which radiation safety performance requirements should be established or modified. In particular, the Commissioner invites comments, preferably supported by scientific and technical data, concerning those performance aspects of computerized tomographic systems that should be addressed in the performance standard for diagnostic x-ray systems. Whereas computerized tomographic x-ray systems are subject to the current performance standard, the Commissioner recognizes that there may be a need for modification of, or addition to, the diagnostic x-ray equipment standard to adequately assure the radiation safety of these systems.

Interested persons may, on or before December 29, 1976, submit to the Hearing Clerk, Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20852, written comments (preferably in quintuplicate and identified with the Hearing Clerk docket number found in brackets in the heading of this document) regarding this advance notice of proposed rulemaking. Received comments may be seen in the above office during working hours, Monday through Friday.

Individuals or organizations wishing to receive additional information or to receive copies of drafts distributed for review during development of these amendments should write to the Bureau of Radiological Health, Division of Compliance (HFX-440), 5600 Fishers Lane, Rockville, MD 20852. This advance notice of proposed rulemaking is being issued pursuant to FDA policy of early public disclosure of rulemaking activities and to solicit comments from interested persons concerning the subject matter of the amendments to be proposed. This issuance is made under the Public Health Service Act, as amended by the Radiation Control for Health and Safety Act of 1968 (sec. 358, 82 Stat. 1177–1179 (42 U.S.C. 263f)) and under authority delegated to the Commissioner (21 CFR 5.1) (recodification published in the FEDERAL REGISTER of June 15, 1976 (41 FR 24262))

Dated: September 27, 1976.

JOSEPH P. HILE,
Acting Associate Commissioner for Compliance.

[FR Doc.76-28558 Filed 9-29-76;8:45 am]

[21 CFR Part 1020]

[Docket No. 76N-0308]

DIAGNOSTIC X-RAY EQUIPMENT PERFORMANCE STANDARD: TOMOGRAPHIC SYSTEMS

Advance Notice of Proposed Rulemaking

The Food and Drug Administration (FDA) is considering amending Subchapter J of Title 21 of the Code of Federal Regulations to change portions of the performance standard for diagnostic x-ray equipment. To be considered in developing the proposed amendments, comments should be submitted by December 29, 1976. Comments received after this date will be considered to the extent possible.

The amendments to § 1020.31 *Radiographic equipment* (21 CFR 1020.31) under consideration would recognize the special operational characteristics of certain types of tomographic x-ray systems

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Office of Academic Vice President for Health Affairs

September 25, 1978

The Honorable James H. Scheuer
Chairman, Subcommittee on Dorestic and International
Scientific Planning, Analysis, and Cooperation
Committee on Science and Technology
U.S. House of Representatives
3274 House Office Building Annex 2
Washington, D.C. 20515

Dear Mr. Scheuer:

I want to thank you and Chairman Teague for your interest in health technology development and assessment. Although I will be unable to appear before the Committee during your September hearings, I appreciate this opportunity to share my views for the record and will be happy to supply you with any additional information should you wish it.

First, I am enclosing a copy of a book entitled, "Technology and the Quality of Health Care," edited by Paul Gertman and me, and published by Aspen Systems Corporation of Germantown, Maryland. The book provides a series of background papers on the subject of technology that I think you will find useful. Pages 263-297 provide a summary of the conference discussions, policy alternatives and recommendations of our staff at the time of the meetings, i.e., early in the Carter Administration. Although the administrative units mentioned in the summary are of little significance, we did conclude--after much reading and the conference--that it is essential that all agencies currently dealing with technology developments in health must be included in any assessment on the part of the federal government. Included should be the NIH, Health Care Financing, National Center for Health Services Research, Office of Technology Assessment and the Office of Science and Technology, as well as any other federal arm currently involved in technology development, assessment and transfer.

While my expertise is limited with regard to the federal strategies on how to deal with health technology development and assessment, I believe I may be in a position to comment on the "management" of health technology and technology diffusion. For a discussion of this nature, it is necessary to first look at how new technologies originate and become introduced into clinical practice.

There are two basic routes by which new technologies are developed. One is via research funded by federal grants and contracts, largely through the NIH. The other is through private sector research, primarily supported by commercial firms looking to market a product.

In the case of federally supported technology development, a large number of devices and systems are currently being explored through NIH-funded research. The key mechanisms currently available to track this research are the study sections and administrative units within NIH. It is through the study section and Council report routes that the earliest input regarding technology development and the closest monitoring of that development is possible. For example, I am a surgical consultant to and collaborator of Dr. Stuart Soeldner at the Joslin Clinic who is developing the artificial beta cell. A large number of federal dollars will have been spent on the development of the beta cell. The artificial beta cell, when it reaches its ultimate state of development, will involve a glucose sensor device which, coupled with other technology, will normalize the blood sugar in diabetics. The technology is elaborate, the development work extensive, and the ultimate product will probably be quite expensive.

The question of its application will be a complex one, as is the case with many costly new health technology developments. Some authorities do not feel that the tight regulation of blood glucose, as is the expected result in the use of the artificial beta cell, is necessary for diabetics. Many disagree. Should the device be reimbursable under Medicare and Medicaid? And, beyond that, how will funding for this device, on a broad clinical scale, compete with other health care priorities? Parenthetically, I think that this development represents an ideal blend of the talents of outstanding basic researchers and clinicians, targeting their efforts on a technology that holds promise of greatly improving the clinical status of diabetics.

This is just one example of the numerous technologies now in the pipeline that could be monitored "early in the game" by interested federal parties--in both the Legislative and Executive Branches. I believe that there needs to be

an office designated at NIH to provide public information on these emerging technologies so that policy-makers can be well informed when making qualitative or quantitative judgements regarding the federal role in both development and assessment.

Private sector support for health technology developments is an equally important and perhaps larger market than federal grants and contracts support. Let us say, for example, that a technologically oriented corporation undertakes to develop an "artificial beta cell." It proceeds with development of the glucose sensor, does the animal field testing and comes up with a product that sells for $20-50,000. It, of course, must go through FDA approval for safety, but that is not the thrust of this discussion. Far more complex are the questions of cost-effectiveness and whether or not this new, effective but expensive device should be paid for through federal and/or private insurance reimbursement. The area of reimbursement policies is one in which the federal government has an established role. The federal government could build on this role, by a route similar to the "certificate of need" process now in effect for new health facilities, giving it a means of examining these technologies, their desirability and possible cost-effectiveness while still in the private sector pipeline. But, of course, a restrictive and anti-free enterprise attitude will rapidly dry up private sector technology innovation, with resultant highly undesirable effects.

All of this, of course, is an oversimplification. There are constant product modifications and very few brand new technologies. I do not believe it will be possible for the federal government to ever "manage" technology along the lines of strict controls. About the best that can be done will be to begin monitoring new technologies as they are evolving and have public discussion of the legal, ethical, financial and equity questions prior to the arrival of the product for sale in the marketplace.

The ultimate cost control vehicle for new technologies is prepayment with an increase in premiums each year based upon increases in the CPI, assuming that initial stable and adequate wage and salary situations exist. Were that the case, a decision to introduce a new technology would be made only after a thorough examination of all factors. Competing prepaid plans may decide to deliver more primary care services, or have lower premiums, in lieu of introducing a new technology.

Ideally, we would follow a plan like that laid out by Alain Enthoven in "Consumer Choice." Unfortunately, we will never again see a free market in health services. However, we can hope to develop a modified free market that has some chance of success. I believe that a combination of a "soft-touch" of government monitoring of technology development coupled with a push from the federal arm toward prepayment that brings some of the constraints of the marketplace to the providers is the best answer to this challenge.

My opinion, then, is that what is needed is: (1) an awareness of emerging technologies by all components of the federal establishment; (2) public discussion of the many complex trade-offs that are critical in evolving technology, applied to each major new development; and (3) some form of outcomes appraisal of major new technologies before they are routinely included in reimbursement processes (best done through the private sector--along the lines of my editorial in the NEJM, September 1978).

I hope these remarks will be of some value to the Committee during its deliberations. Again, please feel free to call on me if I may be of additional assistance.

Very sincerely yours,

Richard H. Egdahl

Richard H. Egdahl, M.D.

RHE:sk
Enclosures
cc: Stuart H. Shapiro, M.D., M.P.H., Committee on Labor and Public Welfare, U.S. Senate.
Dr. Gilbert Omenn, Office of Science & Technology

Illustrative Material Submitted by Dr. Egdahl

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CAT SCANNERS AND PHEOS: DIAGNOSTIC AND POLICY ISSUES

A report by Stewart et al. in this issue of the *Journal* suggests that pheochromocytomas can effectively be localized by computerized axial tomographic (CAT) scanning. This commentary views that finding from the dual perspective of the endocrine surgeon's need for accurate preoperative localization of the adrenal medullary tumor and the health-policy analyst's special interest in the introduction, and financing, of new technologic advances in medicine.

Patients with the clinical symptoms and chemical findings of pheochromocytoma are often referred for radiologic localization at about the same time that the surgeon becomes involved in consultation. Elective adrenal arteriography has proved to be both accurate and safe as the prime method for localization of pheochromocytomas. Three basic questions are raised as a result of this provocative paper. First of all, can CAT scanning *replace* angiography in the diagnosis of pheochromocytoma? If the answer to this question is yes at the current state of knowledge, CAT scanning would have made its case, and angiography would rapidly fade as a localizing procedure in this disease. If not, does it *add measurably* to the angiographic diagnosis? If the answer to the first question is no, and to the second yes, is CAT scanning for pheochromocytoma *cost-effective?*

The authors suggest that the use of computerized axial tomography should "all but eliminate the need for potentially hazardous arteriographic studies" although in a paper from the same clinic in 1974,[1] it is stated that "the arguments against arteriography are mainly related to the deaths reported in the early literature and are not valid today." Christenson et al.,[2] reporting from Nashville on a series of 16 pheochromocytomas, state, "No mortality nor significant morbidity has been related to arteriography during the past sixteen years." Our experience is similar. However, there will be more discomfort associated with an invasive procedure (arteriography) than with a noninvasive one (CAT scanning). In my experience, arteriography can be particularly useful in demonstrating unusually vascular tumors, localizing aberrant vessels that can be watched out for at operation, and, as I have seen on two occasions, visualizing small, ectopic tumors that might have been missed at operation. Therefore, although the results of CAT scanning for pheochromocytoma presented in this initial report are quite impressive, I want the added features of arteriography, and so would not currently replace the vascular procedure with the CAT scanner.

It does appear to supplement angiography. A recent paper by Wittenberg et al.[3] includes a case of pheochromocytoma that was revealed by CAT scanning and later confirmed by angiography. Since, in the Cleveland Clinic experience, a tumor was revealed on CAT scanning that did not show up on arteriography, the technic has potential for localizing an

occasional tumor that is not demonstrated by arteriography, so that it might seem attractive to use both procedures.

The third basic question shifts to the public-policy perspective and complicates the analysis. Is the addition of CAT scanning to the diagnostic work-up of a patient who has had selective adrenal arteriography worth the cost?[4] No one can answer this question at present because the technology is constantly changing and generally accepted methods for cost-effectiveness analysis of new clinical procedures do not exist. The policy issue centers around the constraints that we wish to apply to developing new technology. Traditionally, there have been few restraints either on the development or on the application of new technology — and none on its being reimbursed by insurers. Recently, there have been suggestions that we develop some kind of "outcomes validation" before new technologies are accepted or worked into federal reimbursement policies.

Constantly evolving new technology and its application would present no problem except for the common perception that health-care costs are out of control. Health-care costs continue to rise faster than the GNP because, over and above the general inflation in wages and supplies and costs due to inappropriate utilization of services, the development and application of new technology accounts for an additional 5 to 10 per cent of costs.

If voluntary cost-control efforts do not work, and I fail to see how they can because of this change in health-care product, there are two potential mechanisms for controlling this additional inflationary force. The first is for the government to establish regulations whereby providers would not be reimbursed for the utilization of new technology before some kind of formal validation of outcomes. That policy would mean the establishment of standards for each new technologic innovation. The other is for the private sector to govern itself effectively. This discipline can be applied only when professional societies are prepared to identify potential problems and when they take it upon themselves to monitor these new technologies. With the information gained, the private sector can then organize systems of care through prepayment with fixed dollars, and management decisions, which depend upon the demonstration of cost effectiveness, can then be made. The current problem is the acquisition and application by the majority of providers of a technology before it has been proved efficacious. As one who believes in consumer choice and a modified market in health services, I hope that a combination of private-sector initiation and the management rigor associated with prepayment will lead toward a private-sector solution of the problems presented by developing new technology.

So what is the bottom line on CAT scanning for pheochromocytoma? I suggest that a relatively small number of centers should use CAT scanning for pheochromocytoma localization during the next few years. During this [illegible] clinicians and radiologists involved should interpret the meaning of the data being developed and give guidance to the institutions that are considering the new technology. What is called for, in effect, is a new form of peer review in which the professions sanction the generalized application of a new technology only when the evidence is sufficiently convincing. If such professional peer-review procedures are not developed, the constantly evolving set of new technologies will receive immediate widespread and excessive application and health-care cost inflation will continue.

If we do not have a health-care cost crisis and if we do not need to restrict health services in any way, as an endocrine surgeon, I should like every one of my preoperative patients to receive both selective adrenal arteriography and a CAT scan to gain the greatest possible diagnostic accuracy. However, if we do have a problem with national health-care expenditures, the government may undertake progressively explicit forms of rationing.[5] To forestall this intervention, the medical profession should develop the peer-review process referred to above. We are not used to doing this kind of review, and have not made major efforts to develop the methodology that will be required. We should.

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Discussion

This study shows that salmonellosis is much more than an inconvenience — it was responsible for complications, operations and hospitalizations of five to six days for previously well persons in all age groups, not just infants and the elderly. It also demonstrates that salmonellosis is expensive not only for those who are ill but also for society because such outbreaks adversely affect the economy.

We estimate, on the basis of reported cases, cheese distribution and attack rates, that 32,000 persons were involved in this one outbreak. Most of those who were ill but whose cases were not reported probably had relatively mild illness, but if their costs were similar to those for persons in this study who were neither hospitalized nor saw a physician (mean of $125 per person), their total cost was substantial ($4,000,000). Such costs, composed of lost wages or output, are direct reduction in gross national product. Since these losses would far exceed total medical costs, which increase gross national product, such outbreaks adversely affect the economy.

The rapid detection of the outbreak and prompt institution of control measures offered an opportunity to define the benefits of surveillance. One can calculate that if all the embargoed cheese had been consumed, the outbreak would have been 74 per cent larger, resulting in additional 175 reported cases and some 23,700 unreported. Projecting from the preceding data, this figure would have resulted in an additional cost for reported cases of $111,405 and for unreported cases of $2.9 million. By comparison, in 1976, salmonella serotyping, the major component of salmonella surveillance, cost the Colorado Department of Health $3,580 (Barr RJ: personal communication).

It has been estimated that over 500 outbreaks of salmonellosis and over 2,000,000 cases occur in the United States each year.[4] Since this is a preventable disease, the cost of public-health programs to detect, control and prevent salmonellosis must be measured against the unnecessary medical expenses and loss-of-productivity costs, which may be more than a billion dollars a year.

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LOCALIZATION OF PHEOCHROMOCYTOMA BY COMPUTED TOMOGRAPHY

Bruce H. Stewart, M.D., Emmanuel L. Bravo, M.D., John Haaga, M.D., Thomas F. Meaney, M.D., and Robert Tarazi, M.D.

TUMOR localization is an integral part of the surgical management of pheochromocytoma. Although the diagnosis may be suspected from the history and physical findings and confirmed by various pharmacologic studies, it is important for the surgeon to know the precise location and extent of the tumor when he is planning its safe and expeditious removal.[1-3] Intravenous pyelography, even with laminagraphic views, has often failed to demonstrate these tumors.[4] Selective arteriography has accurately demonstrated the blood supply and extent of most pheochromocytomas, but is an invasive technic with serious potential complications, including hypertensive crises.[5-7] Adrenal-vein and vena-cava sampling of blood for catecholamines can help localize tumors in selected cases, although it, too, is an invasive procedure and is of little help in estimating size and extent of disease.[8,9]

Computerized axial tomography should theoretically demonstrate the presence, size and extent of both adrenal and extra-adrenal tumors without serious toxicity. This report summarizes early experience with this new diagnostic method in the management of patients with pheochromocytoma.

Patient Material

Eleven patients with proved pheochromocytoma underwent intravenous pyelography with laminagrams, selective renal arteriography and computerized axial tomography of the abdomen for purposes of localization of the tumor, estimation of size and extent of disease and determination of relative accuracy of each diagnostic test. In eight of these patients, the tumors were solitary and of adrenal origin; in one they were bilateral, and in two they were malignant (one of these was extra-adrenal). Satisfactory localization of the tumor was accomplished by pyelographic studies in only four (36 per cent), by selective angiography in 10 (91 per cent) and by computerized tomographic scanning in 10 of the 11 cases (91 per cent).

An aortogram and selective renal arteriogram, obtained from another institution and of somewhat less than optimum quality, failed to demonstrate the presence in one patient of a large avascular pheochromocytoma that lay just anterior to the upper pole of the left kidney and was clearly shown on the computerized tomographic scan. In another case the scan was interpreted as normal, whereas the angiogram demonstrated a 2.5-cm vascular pheochromocytoma arising from the right adrenal gland and lying anterior to the upper pole of the right kidney. In retrospect, the scan did indeed demonstrate the tumor, although at a lower level than one would anticipate the tumor to be found. In a third case the angiogram suggested cancer because of vascularity in the lower part of the kidney adjacent to the adrenal tumor, but upon removal of the tumor, there was no direct invasion into the kidney; in a fourth case the scan indicated direct invasion of the kidney that was not borne

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Table 1. Relative Accuracy of Various Localization Procedures in 11 Patients with Proved Pheochromocytoma.

Diagnostic Study	No. Correct	Erroneous Diagnosis or Cancer
Intravenous pyelography	4/11 (36%)	—
Selective angiography	10/11 (91%)	1/11 (9%)
Computerized tomography	10/11 (91%)	1/11 (9%)

out at operation and was not suggested on angiography. In a final case, the scan suggested the presence of a second tumor in the right paracaval region, whereas in fact this was only a prominent uncinate process of the pancreas.

All patients were studied by the 18-second Delta scanner,* and the use of intravenous contrast medium did not enhance the imaging of any of these adrenal tumors. Relative accuracy of the scan versus other diagnostic studies is summarized in Table 1.

Discussion

Computerized axial tomography has been available at the Cleveland Clinic Foundation since 1974, and has proved to be a valuable diagnostic aid in patients with a wide spectrum of genitourinary disorders.[10] It not only has been able to define the presence or location of various renal and adrenal mass lesions but also is capable of assessing the extent of these tumors in relation to surrounding structures.[11,12] It has the further advantage of being noninvasive and nontoxic. Our initial experience with pheochromocytomas indicates that scanning can detect the presence, location and extent of these tumors as accurately as selective angiography and with less risk. Although the test is usually not diagnostic in patients with small adenomas, such as those seen in primary aldosteronism, it appears highly accurate in detecting tumors over 2 cm in size. Although precise data are lacking in the literature, the vast majority of pheochromocytomas exceed 2 cm in size. In reviewing our most recent 33 cases, the tumors ranged from 2 to 16 cm in diameter, only three being less than 3 cm in size.† Thus, it appears that the number of pheochromocytomas that would be potentially missed on the scan because of small size should be extremely low.

From the standpoint of practical management, the use of computerized axial tomography should all but eliminate the need for potentially hazardous arteriographic studies in the preoperative detection and localization of pheochromocytoma. We now have sufficient confidence to operate directly on patients with positive biochemical studies if the scan satisfactorily localizes the pheochromocytoma. In fact we have done so in three additional patients successfully treated since the final preparation of this report.

It is now suggested that patients with suspected pheochromocytoma be examined first with the usual biochemical and pharmacologic studies, and the tumor then localized by computerized axial tomography. Nephrotomography and selective arteriography will not be necessary unless the scan fails to identify the tumor. Similarly, selective caval sampling for catecholamines should be done only when extra-adrenal tumors are suspected or when a primary adrenal tumor cannot be satisfactorily demonstrated by other technics.

*Ohio Nuclear Corporation, Solon, OH.

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